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Dear AUTM Members:

The Council on Government Relations (COGR), with the assistance of several AUTM members, has produced two very helpful documents providing answers to some of the more commonly asked questions of technology transfer professionals.

These brochures can assist persons new to our profession, including your public relations and governmental affairs departments, to understand the role of the technology transfer office. They may also help them to respond to questions from the press.

COGR and AUTM hope that you will find the information useful.

Sincerely,

H.S. Duke Leahey

AUTM President

PD:hs

Enclosures:

University Technology Transfer - Questions and Answers The Bayh-Dole Act - A guide to the law and implementing regulations

University Technology Manage Journal of the Association

AUTIM

Association of University Technology Managers

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The Journal of the Association of University Technology Managers

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EDITOR'S PREFACE

Volume V of the AUTM Journal presents four original papers concerning the art and practice of technology management. Once again, the papers focus on topics that were on people's minds throughout the year. With the publication of the comprehensive AUTM Licensing Survey, we are now able to compare our institution's statistics with those of other institutions, in our continuing quest for the answer to the question: "How Are We Doing?" Two of the papers in this volume describe efforts to quantify technology transfer in some way. A third paper concerns a survey carried out in response to an article in last year's Journal. Another records the testimony by an AUTM colleague at a public hearing in Washington, D.C. in October 1993.

In his paper entitled "Licensing Engineering Inventions - A Process Planning Model," Daniel Massing describes the unique problems involving commercialization of inventions from the engineering fields, as opposed to those arising out of the life sciences. He suggests a possible method of formulating a model by which engineering inventions may be more easily evaluated for commercialization. This attempt to quantify technology transfer functions by means of process planning could lead to a valuable technique for the technology manager.

On October 25, 1993, the Public Meeting on Regulations (37CFR, Part 401) Relating to Rights in Inventions Made with Federal Funding by Nonprofit Organizations and Small Business Firms was held in Washington, D.C. Howard Bremer spoke on behalf of the Council on Governmental Relations (COGR), giving an historic overview in support of the benefits of the Bayh-Dole Act of 1980. We publish this testimony here in its entirety because the Bayh-Dole Act was the vital step toward allowing the transfer of innovations from the academic setting to the public sector.

As a result of the article by B. Jean Weidemier in Volume IV of the AUTM Journal, entitled "Ownership of

LETTERS TO THE EDITOR

Special Look from the State Perspective

To the Editor:

This issue (IV '92) of the AUTM Journal contained a number of useful and interesting articles which I was pleased to be able to share with colleagues on campus. Thanks for including a special look at technology transfer from the state university perspective.

Margaret P. Schachte Director, Research Administrative Services and Planning Medical University of South Carolina

Universities Not Liable for Harm

To the Editor:

I found Mr. Hauth's article entitled "Theories Opposing the Imposition of Product Liability on (University) Patent Licensors" (AUTM Journal IV '92) quite interesting and relevant. Perhaps another reason behind the reluctance to find universities liable for harm caused by end products which employ their

licensed technology is the lack of control that universities have concerning the risks to end users their licensed technology. Universities are unlikely to be involved in performing final tests. evaluating end-user packaging the product, marketing the merchandise, or making go or no-go decisions. Without such control, it is difficult if not impossible to find universities liable for the harm caused to the users of the licensed technology. This is also a reason why licensees allow broad indemnity clauses...

Sincerely,
Daniel Broderick
Licensing Associate
Technology Transfer Program
Northwestern University

The editor welcomes letters that comment on articles in this issue or that discuss matters related to the management of intellectual property. Letters need not be pertinent to any one article.

Early responses are encouraged. Letters should be concise and clearly stated. Include your name, job title, and company affiliation.

Licensing Engineering Inventions A Process Planning Model

Daniel E. Massing

I. Summary

Industry development of university-licensed inventions can be likened to any game of chance. Successes are the result of a combination of often unplanned or chance events that collectively link to meet a commercialization objective. With misapplication or failure of any link, unpredictable results lead to failure to reach goals. The ongoing process of invention commercialization can continue to be governed either by chance or by more predictable means by using process planning methods that are proposed in this study.

The discussion will focus on licensing inventions from engineering school research in the physical sciences. A concept called "Linkage Classification/Development" is defined as the process by which post-research inventions must be linked by a unique combination of development and funding methods to bring the invention to a point of commercial (industrial) attractiveness. Such methods must be chosen from a myriad of possible resource combinations such as state,

^{*} Daniel E. Massing is Associate Director, Technology Transfer Services, The Research Foundation of SUNY, Buffalo, NY 14260-0001. This paper was originally presented at the 1993 AUTM Annual Meeting in Dallas, Texas.

[©] Daniel E. Massing

volume, another factor augments invention transfer as well; that of the process itself. Because of regulatory control, the process of commercialization has been structured so that a life science, health-related invention usually must follow a prescribed path in moving from the university laboratory to the marketplace. Such a process inherently provides both commercial recognition of invention state, and intrinsic valuation of the invention based on intellectual property and regulatory information. Hence manufacturers are easily attracted to inventions that are recognizable relative to their markets, and are developed within both the company's expertise and regulatory compliance capabilities. Placed in a simplified context, technology transfer is driven by a commercial "pull" instead of a university "push" (ref. 2).

Commercialization of physical science and more specifically engineering-based inventions does not follow a similar process except in those cases involving product or worker safety compliance. Lacking recognizable milestones similar to those in the life sciences, the licensing of engineering inventions tends to follow a random pattern with success resulting more from opportunity rather than from intent. Put in familiar terms, commercialization is initiated by "push" rather than "pull" strategies.

Engineering inventions of measurable status and commercial relevance could be transferred more effectively (more often and with better licensing results) if there existed an industry recognizable tech-transfer planning process. To many in the licensing field experienced with physical science inventions, the goal of process planning may seem lofty. Indeed, the author has no illusions about the reality of achieving a working, validated, and accepted process model all within this millennium. As a student of and strong believer in

Lack of correlation between external funding 6) requirements and development milestones and equivalent commercial development (i.e. same invention born and bred internally in the company).

Approach to Tech-Transfer Process Model Development IV.

Motivation A)

University licensing of its intellectual property should be professionally considered as a management function. Hence, the organization title, "The Association of University Technology Managers," reflects the formal duties and responsibilities of members engaged in the profession. Unlike other management practices (operations, finance, etc.) the practice of techtransfer lacks planning tools sufficient to predict even the most fundamental results in a "what-if" situation. Consider the following situations, which reflect the start of tech-transfer processes:

- The inventor, having disclosed, asks how, if, and when the invention will be commercialized.
- The licensing professional, disclosure in hand. ponders the question commercialization potential and university investment to gain a license.

Because of the absence of process-specific planning tools, neither of these scenarios can benefit from available planning methods without extensive preliminary investigation.

alternative tech-transfer paths (i.e., perform "what-ifs").

- 3) Use process-model-solution procedures based on critical-path calculation methods, i.e., traditional Industrial Engineering Critical Path Project Planning Method.
- 4) Classify tech-transfer subprocesses in terms of attribute or numerical scales to permit quantitative process measurement.
- 5) Expand classification to create comprehensive inventory of tech-transfer resources for use in database approach to process planning.
- 6) Continue refinement of planning tool by using licensing case studies to validate or improve process model.
- 7) Encourage industry recognition and acceptance of planning process as measurement of invention value versus cost/risk of commercialization.

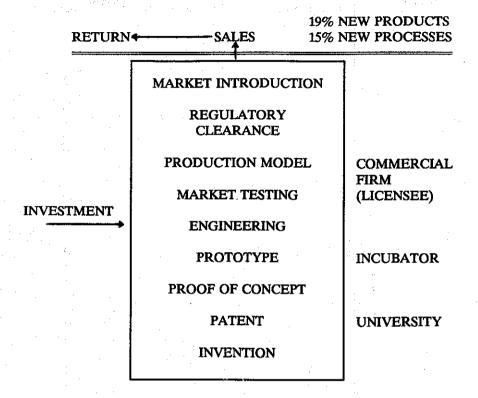
V. <u>Comparison of Existing Physical and Life Science</u> <u>Technology-Transfer Processes</u>

For the purpose of classification, we will use a broad definition of the science fields as a means to distinguish invention types. Thus;

Life Science Invention: All works derived from the chemistry discipline.

Physical Science Invention: All works derived from the physics discipline.

INVENTION LIFE CYCLE - PHYSICAL SCIENCES



VI. Model Formulation

A fundamental process definition is used to illustrate a possible relationship to the tech-transfer process. Using the concept of a process transfer function, we may begin to formulate both a process analog and an elementary model formulation.

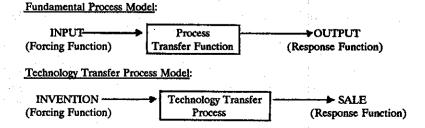


Table 1: Classification of Sub-Process Characteristics

* *	<u>COMPONENT</u> <u>MEAS</u>	UREMENT
		(Scalar)
		(Discreet)
A)	Intellectual Property Development	
	· Quality of Invention	(S)
	• Strength of Intellectual Property	, ,
	Protection	(S)
•	• Engineering/Technical Discipline	(D)
B)	Solicitation of Commercial Interest	
	· Process Plan	(D)
	· Commercial Recognizability of In	
	· "Push" or "Pull" Strategy	(D)
	• Interaction	(D)
	• Market Need	(S)
	· Funding Source/Magnitude	(S)
C)	License Preparation & Negotiation	
	· Tech-transfer Facilitator/Organiza	ation (S)
D)	Product Development	
	· Commercial Research "Intensity"	(S)
	· Regulatory Process Control	(S)
E)	Business Development, Marketing,	
	and Manufacturing Integration	
	· Organizational Capacity	(S)
	• Enterprise Integration	(S)
	(Concurrent Engineering,	
	Total Quality Management, etc.)	

Selection of most likely time values for respective paths may be based on estimates from experience and/or available references. A systematic way of choosing minimum and maximum times can employ scaling relationships defined previously in Table 1. By using an integer value (1-10) as a weighting factor to reflect process uncertainty, a suitable multiplier may be used to calculate respective upper and lower-bound time values. An example of such path time estimation applied to two invention cases is given in Section IX.

VIII. Quantitative Measures from Process Planning

A) Previous Efforts to Quantify Tech-Transfer **Processes**

A brief literature search provided three relevant references. In the first, Zhao and Grier (ref. 4) propose a conceptual tech-transfer model including causative factors of funding (F), research intensity (I), and research work force mobility (M). The model is used to study the correlation between technical income (T) and the model factors F, I, and M. A logarithmic multiple regression model, with (e) as an error term is employed as a statistical test of model validity as follows:

$$lnT = A + B lnF + C lnI + d lnM + e$$

authors report good correlation The squared=.77) using data from a sample of tech-transfer cases in mainland China.

A second reference Mansfield (ref. 5) reports sales from products commercialized from academic research sources. In addition, the reference details average time lag from academic disclosure commercial introduction from several classifications. A multiple regression model is used to calculated time within a prescribed tolerance is demonstrated to show the effect of minimum and maximum component path time variability on total process time.

Method	Process Path	Completion (Months)	
Incubator 1	A-E-I-M	15.8	0.205
Incubator 2	A-F-J-L-M	21.7	0.197
CRADA	B-G-J-L-M	24.4	0.218
Direct	C-J-L-M	22.7	0.208
Third Party	D-H-K-L-M	27.5	0.236

A valuable by-product of this method of process planning is the ability to use resulting temporal information to convert to a cost basis for both invention valuation and cost-to-commercialize.

Using the above comparisons, it is possible to define alternative costs between nodes by applying an expenditure rate (dollars-per-month) parameter to each path. Comparison of alternative paths can then be performed on the basis of total time and cumulative process cost. Further, it is feasible to estimate intellectual property value through application of alternate time-to-market calculations using the method demonstrated by Razgaitis (ref. 5). Given the estimated commercialization time, one may select a risk factor (k. discount rate) based on invention classifications identified in the reference. With the time interval determined, the present value of the invention may be calculated based on the future value of a series of specified royalty payments under a proposed licensing arrangement applied over the commercialization period.

	COMPONENT		REMENT Case B
A) .	Intellectual Property Development		
	 Quality of Invention Strength of Intellectual Property	8	, 7
	Protection • Scientific Discipline	8 Mech. Eng.	5 Comp. Sci.
В)	Solicitation of Commercial Interest	*.	
	Process Plan Commercial Recognizability	yes	no
	of Invention • "Push" or "Pull" Strategy • Interaction	6 push no	4 pull yes
	 Market Need Funding Source/Magnitude	5 3	8 7
C)	License Preparation & Negotiation		
	• Tech-Transfer Facilitator/ Organization	6	8
D)	Product Development		
	Commercial Research "Intensity"Regulatory Process Control	5 5	7 2
E)	Business Development, Marketing, and Manufacturing Integration		
	 Organizational Capacity Enterprise Integration (Concurrent Engineering, Total Quality Management, etc.) 	4 2	8 6

The calculation of respective path and resulting total process times based on the numerical solution method previously referenced is tabulated below:

Case A:		P 2			
	a1 =	0.2	a2 =	0.5	
	Avg.		most		
(i)	<u>(i)</u>	<u>tmin</u>	<u>prob</u>	<u>tmax</u>	<u>t e</u>
A	8.0	13.6	14.0	15.8	14.2
В	5.0	7.6	8.0	9.6	8.2
C	5.0	5.7	6.0	7.2	6.2
D	4.0	4.7	5.0	6.3	5.2
E	2.0	8.8	10.0	15.0	10.6
: 1	Total				44.4
			**		mos
Case B:					
	Avg.		most		
<u>(i)</u>	_(i)	<u>tmin</u>	<u>prob</u>	<u>tmax</u>	<u>t e</u>
A	6.0	13.4	14.0	16.3	14.3
В	8.0	7.8	8.0	9.0	8.1
C	5.8	5.7	6.0	7.0	6.1
	Total				28.5
			• .		mos

Future Process Model Development

The preceding justification and formulation of a process model for commercialization of engineering inventions is, by necessity, both conceptual and preliminary. As with any process planning method, experience must be classified and then systematically applied to produce a worthwhile approach. The resulting objective formulation must then be validated against comparable real processes to attain any value as

An example of process linkage in this field (ref. 7) follows to illustrate the effect of regulatory actions on the commercialization cycle. In contrast, the physical science or engineering-based tech-transfer version cannot be demonstrated in similar format.

CLINICAL INVESTIGATION TIMELINE

CLINICAL PHASE

R & D	Pre-Clinical	Phase I	Phase II	Phase III
Scientific Review	Scientific Review	Scientific Review	Scientific Review	Scientific Review
	CRO/PI Decision Select CRO Select PIs			,
Animal Studies				
GLP Side Effects	Manufacturing GMP Label Scale Up			
Clinical Indications				
	Protocol & Amendments	Protocol & Amendments	Protocol & Amendments	Protocol & Amendments
Literature Search	Dev. Informed Consent			
	IRB Approval & Monitoring	IRB Approval & Monitoring	IRB Approval & Monitoring	IRB Approval & Monitoring
Stability Studies	CRP/PI Monitoring	CRO/PI Monitoring		CRO/PI Monitoring

Nomenclature:

CRO: Contract Research Organization

PI: Principal Investigator

GLP: Good Laboratory Practice GMP: Good Manufacturing Practice IRB: Institutional Review Board

The intent of this previous illustration is to show a structure that could lead to a database design with modest beginning and future flexibility. The task of completing initial design and cataloging is significant and justifies solicitation of sponsorship to attain proper funding and recognition of need. From the author's perspective, such recognition would be motivation to document and publish further results as follow-on to the works presented in this paper.

XI. Conclusion

The process described above, including methods for computer implementation, has been demonstrated in an effort to identify a quantitative means to compare tech-transfer alternatives. Considerable effort is still necessary to classify process components that will represent near-actual conditions in practice. Specific need is focused on process component time and risk quantification so that the proposed numerical analyses provide a realistic measure of time-to-market and related probability. A logical next step would be to catalog processes according to respective times and uncertainty measures using the approach proposed earlier. A succeeding step would then lead to database formulation and validation testing for ability to discriminate between alternative tech-transfer processes. A final step would compare actual case histories against predictive measures as a means to establish full scale validation of the database mechanization.

tech-transfer practitioners encouraged continuation of this work informally. The nature of these recommendations suggests that ongoing development be performed in an informal collaborative arrangement involving perhaps three institutions. This approach would provide the diversity of experience needed to perform the process component classification

- 1. Cary, C., "A Decade of Progress," The Research Foundation SUNY, Buffalo, NY, Mar. 1991.
- 2. Article "Other People's Technology," *Technology New York Report*, Vol. 11, No.1, Jan. 1993.
- 3. Elsayed, E. and Boucher, T., <u>Analysis and Control of Production Systems</u>, Prentice-Hall, Inc., 1985.
- 4. Zhao, H. and Grier, D., "Factors Influencing Technology Transfer: The Case of China," *Journal of Technology Transfer*, Vol. 16, No. 4, Fall 1991.
- 5. Mansfield, E., "Academic Research and Industrial Innovation," Elsevier Science Publishers, B.V., Jan. 1990.
- 6. Razgaitis, R., "Some Considerations on Establishing the Commercial Value of IP of Early-Stage Technologies," AUTM Licensing Course, Oct. 1992.
- 7. Weiner, J., "Biotechnology Viewpoint-Selecting Risk Management Service Providers," New York Biotechnology Association Annual Meeting, Sept. 1992.
- 8. Morrison, D., "Texas Innovation Network Thinks Big," Technology Access Report, Feb. 1993.

Testimony on the Effectiveness of the Bayh-Dole Act

October 25, 1993 Council on Governmental Relations (COGR)

Howard W. Bremer*

Purpose of the Invited Testimony

The Office of Technology Commercialization, in the Department of Commerce, invited a review of the Bayh-Dole Act (P.L. 96-517), as amended by P.L. 98-620 and the implementing regulations, issued March 12, 1984 at 37 CFR Part 401. This allows a welcome dialogue between the Department of Commerce, which is assigned regulatory authority and is also charged to promote commercialization, and universities, which conduct the bulk of the basic research carried out in the United States and which develop scientists and engineers who produce new knowledge and new technologies.

On behalf of its membership, which comprises 137 of the leading research universities in the United States, the Council on Governmental Relations appreciates the opportunity to review the effectiveness of the Bayh-Dole Act over the past decade. COGR believes the principles upon which the Bayh-Dole Act were based and the Act itself were sound public

^{*} Howard W. Bremer, Consultant, c/o Wisconsin Alumni Research Foundation, 624 North Walnut St., Madison, WI 53705. This paper was originally given as testimony at the Public Meeting on Regulations (37 CFR Part 401) Relating to Rights to Inventions made with Federal Funding by Nonprofit Organizations and Small Business Firms in Washington, D.C., on October 25, 1993.

business is in the public interest; and, perhaps most significantly

(4) that the existing federal patent policy was placing the nation in peril during a time when innovation was becoming the preferred currency in foreign affairs.

It was also a recognition that the inventor is a significant factor in the technology transfer equation. Through the "title" policy the government had no access to the inventor to provide the necessary bridge from invention to innovation. Without that bridge, the licensing of university-generated technologies, which tend to be embryonic in nature, could not be achieved.

In contrast, Bayh-Dole, by giving the universities the first option to retain title to inventions, permitted them to make informed decisions about patenting and to effectively manage the marketing of their patents to industry; all with the help of the inventor who best understood the technology. Moreover, the natural collaboration between the inventor and his university was enhanced through the incentive afforded by the university's sharing licensing revenues with the inventor--a principle that is now a requirement under the law.

Probably the single most important aspect of Bayh-Dole was to insure the certainty of title in the universities to inventions made with government funds. This feature provided the major impetus to new and expanding university-industry relationships. The certainty of title and uniform government-wide implementing regulations provide the stability that has been the key element to the success of Bayh-Dole over the past decade.

Also of great importance to academe is that freedom to publish is not restricted by Bayh-Dole. While premature publishing will have a significant effect on patenting, not publishing will have a significant effect upon the credibility and strength of the university research work product. It is in the best

and that government policy should continue to nurture.

The drug industry showed the greatest dependence on academic research with 44% of its new products and 37% of its processes depending upon such research. The information processing industry was also found to rely heavily on academic research with 28% of its products and 27% of its processes having a dependency on recent academic research. The metals industry also showed a high degree of dependence on recent academic research with 22% of its products and 21% of its processes being so dependent. (NSF: Science and Engineering Indicators-1989.)

Collaboration between universities and small business has increased as a result of the Bayh-Dole legislation. In testimony before the House Small Business Subcommittee in June 1993, NIH Director Bernadine Healy presented preliminary data from a survey of one hundred federally funded U.S. research universities. Of the approximately 375 research support agreements reviewed by NIH, 44% were with small business. A different set of data confirms the same development trend: a 1992 GAO study found that of 197 exclusive licenses granted during 1989-90 for technologies developed in whole or in part with NIH or NSF funding, 146 (or 74%) were granted to small U.S. business.

The government investment in university research also flourished under Bayh-Dole when viewed in terms of inventions generated that could be licensed to industry. The surge in patent applications and patents issued illustrates a dramatic success story. The General Accounting Office reported in May 1992 on the performance of 35 major research universities. Out of 197 exclusive licenses mentioned above, more than 175 were for technologies developed with federal (NIH) funding. The 1,155 patents granted to U.S. universities in 1990 accounted for 2.4% of all U.S. origin patents. This figure compares to 1 % in 1980. NSF reports that in 1970, one in eight university patents originated from a biomedical or health related invention. That

agency decides that such restriction will better promote commercialization of an invention. Under Bayh-Dole an "exceptional circumstance" may be declared only: (1) when the contractor is a foreign company; (2) when the agency determines that restriction or elimination of the right to retain title will better promote the policy and objectives of Bayh-Dole; (3) for national security; and (4) for certain DOE-funded GOCOs. To be sure, commercialization is one of the enumerated policy objectives of Bayh-Dole, but there may be other objectives just as important that might be violated under an "exceptional circumstances" exemption based only on commercialization. To invoke the "exceptional circumstance" exemption, other prescribed procedures must be followed which are under the control of the Department of Commerce.

The "exceptional circumstances" exemption does provide flexibility to the government for programs that have specific purposes or goals not well served by universities retaining title to inventions. However, there is opportunity for mischief and misuse of the exemption: witness the Advanced Battery Consortium. If one ties an exemption only to the commercialization criterion, there is a presumption that a government agency is in a better position to determine what will better promote commercialization of an invention. The past performances of agencies in the transfer of technology do not support the proposition that they are more qualified than universities to make such determinations.

In any event, the universities believe that the Department of Commerce, as the lead agency under Bayh-Dole, should carefully and rigorously review any request for an exemption under the "exceptional circumstances" provision and should apply well understood criteria for approving exceptions.

created high technology jobs, and spawned a robust U.S. biotechnology industry."

Small business is frequently the test bed for embryonic university technologies and has benefitted to a very large extent. The government is comforted in knowing that taxpayer dollars lead to development of products that advance the health and safety of its citizens. Industry can rely on a source of data and a pipeline of manpower that feeds its production processes. All sectors of society enjoy both the protection and benefits provided by the Bayh-Dole Act.

Change should be sought where change is needed to correct errors or mitigate inequities. However, change merely for the sake of change, should be avoided as counterproductive.

Development of an (Employee) Intellectual Property Assignment Agreement

Jean A. Mahoney*
Diane C. Hoffman*

I. <u>INTRODUCTION</u>

"Employees and visitors in a position to invent should be required to sign Invention Assignment Agreements as often as employees sign W-2 forms."¹

But:

What components should be included in an assignment agreement?

How far-reaching should the agreement be with respect to ownership of inventions?

Should it include all aspects of intellectual property, including software and copyright?

Should it cover works related only to sponsored projects or to all research related activities, works made for hire, and those produced through the use of the institution's resources?

^{*} Jean A. Mahoney is Manager of Technology and Trademark Licensing, Princeton University, Princeton, NJ 08544. Diane C. Hoffman is President, Diane C. Hoffman, Inc., a consulting business, 23 Perrine Path, Cranbury, NJ 08512.

[©] Jean A. Mahoney and Diane C. Hoffman

IV. **MAJOR COMPONENTS**

- 1) Title
- 2) Compliance Requirements
- 3) Office to Which the Signed Agreement Should be Returned
- 4) Inventions Made in the Course Of...
- 5) Definition of Resources Used
- 6) Assignment of Rights
- 7) **Documentation Requirements**
- 8) Signee and/or Principal Investigator Responsibilities
- Conflict of Interest Provisions 9)
- 10) Effective Date
- 11) **Binding On**
- Survival Clause 12)
- 13) Miscellaneous Clauses

1) Title

Of the eighteen sample agreements received, ten different titles were used. These are provided alphabetically as follows:

Copyright and Patent Agreement Intellectual Property Agreement Invention and Patent Agreement Inventions and Proprietary Information Agreement Participation Agreement Patent Agreement Patent and Invention Agreement Patent Policy and Agreement Patent Understanding Patent Waiver and Release Agreement

Intellectual Property. The products of the mind.⁷ More specifically defined, all inventions, copyrightable materials, computer software, semiconductor mask works, and trademarks. Tangible Research Property may also be captured in the definition of intellectual property. as was done in one of the sample agreements.8

Participation. A taking part or sharing.⁹

Patent. A grant of certain rights by the Government. The right conferred by the patent grant is, in the language of the statute and of the grant itself, "the right to exclude others from making, using, or selling" the invention.¹⁰

Proprietary Information. Private information that is developed and exclusively owned by an individual or company. This information is not known by others nor is it a part of the public domain 11

Release. The relinquishment of a right, title, or claim to another. 12

Waiver. The intentional relinquishment of a right, claim, or privilege.¹³

Understanding. Specified judgement or outlook in a matter; opinion; interpretation.¹⁴

The authors selected the title "Intellectual Property Assignment Agreement" for boilerplate agreement, as it covers all items mentioned in the Intellectual Property definition and in the Assignment definition (the rights are being transferred from the employee to the

The office identified in the boilerplate agreement is the university's Technology Transfer Office.

Inventions Made in the Course of... 4)

In review of the agreements for "what inventions" were covered under the stated terms and conditions, two trends were identified:

- a) Agreements that were developed in response to 37 C.F.R. § 401.14 (f), which requires that a written agreement be established with all employees (other than clerical and nontechnical employees) to disclose promptly each subject invention made under a sponsored program and to execute all papers necessary to file patent applications. 15 These agreements cover only those inventions produced as a result of a sponsored project.
- b) Agreements that were developed to meet the federal requirement and to define the institution's rights to all intellectual property produced by its employees. These agreements cover all works (as defined by "Intellectual Property" above) produced if:
 - in the course of employment or as a non-employee (relationship defined);
 - through research, including but not limited to sponsored research;
 - with the use of university resources;

Rather than attempting to define or narrow "resources," the boilerplate agreement simply states "...use of university resources."

6) **Assignment of Rights**

In conjunction with the provisions covering when an item is subject to the Intellectual Property Assignment Agreement ("Inventions Made in the Course Of ... "), the language surrounding the "Assignment of Rights" is crucial.

We extracted sample language from the agreements to provide the background for the final paragraph selected for the boilerplate agreement. These sample paragraphs are listed and divided into the following below subcategories:

- Language that defines the items subject to a) assignment as "inventions or discoveries."
- b) Language that defines the items subject to assignment as "patentable inventions or discoveries."
- Language that limits the items subject to c) assignment to those produced under a sponsored project.
- Notations on "Copyright" and "Computer d) Software."
- Suggested language for the boilerplate e) agreement, which is included under the subheading, "Amalgamation of Terms."

assign all rights to such discoveries or inventions and any and all patents and patent applications thereon..."

Limited to Sponsored Projects c)

hereby agree...as follows: "To do whatever is necessary to apply for and take out patents and to assign in writing to the University that right, title, and interest in and to inventions and patents which result from grants and contracts in which I have participated."

"As a condition of my participation in any extramurally sponsored research or extramurally supported activity..., I hereby agree to disclose promptly ... any invention conceived and/or reduced to practice by me, whether solely or jointly with others, resulting in whole or in part from such extramurally supported activity. I further agree that I will comply with the provisions of any agreement between the University and any sponsor...in assuring that the sponsor's rights, including rights in inventions and patents, are fully protected."

Copyright and Computer Software

Some of the agreements included an explicit provision for copyrightable works, in addition to the above terms.

Computer software is listed explicitly in only two of the agreements. However, these developments might be included implicitly in the institution's intellectual property agreement through a compliance requirement with the

7) **Documentation Requirements**

37 C.F.R. § 401.14 (f), requires that "...all papers necessary to file patent applications..." be executed. Even without this federal requirement. it is prudent for a university to include a requirement in its agreement for the proper execution of all papers necessary for the filing, maintenance, or enforcement of any and all claims.

The following paragraph was developed by combining key phrases identified agreements. The key words which should be included in any intellectual property agreement are underlined for emphasis in this article, but are not underlined in the boilerplate agreement (paragraph # 2).

"To disclose promptly in writing through the Technology Transfer Office any such Intellectual Property, to assign all rights to such Property to University or its designee for this purpose, or such other agency as the University may direct, to execute all necessary papers, and to cooperate fully (at no out-of-pocket cost to myself) with the University or such designee to enable the University to obtain, maintain, or enforce for itself or its designee, patents, copyrights, or other legal protection for such Intellectual Property."

8) Signee and/or Principal Investigator Responsibilities

The responsibilities referred to in this section are those that require a commitment or agreement on the part of the signee or a conflict with this agreement.

- Blank lines may be provided for the listing ii) of potential conflicts.
- I will not, after signing the agreement, iii) enter into any contractual arrangement in conflict with the agreement.
- I agree not to disclose to university or use iv) in work, any proprietary information belonging to any prior employers or any third party.
- In the event of a conflict, waivers or releases will be obtained to allow the signing of the agreement.
- If the waivers or releases are not obtained from third parties, I understand that I may be precluded from participating sponsored projects, or in other university activities relevant to this agreement.

10-12 Effective Date, Binding On..., and Survival Clause

Because these items are closely related, they are addressed together in this section. Fewer than four of the agreements included a statement for all three of these terms.

Referring to Weidemier's article (Notes #17) on "consideration," the effective date of the boilerplate agreement is "the entire term of my employment." It includes a survival clause, "...this Agreement...shall continue after termination of modified or terminated, except in writing signed by authorized officials.

The inclusion of a witness signature.

IMPLEMENTATION

The procedures employed to implement the intellectual property agreement are not focused on in this article. However, a university should at minimum:

- 1) Determine the desired scope of the agreement prior to adapting or modifying the boilerplate agreement;
- 2) Consult with university counsel to determine if the agreement is legally binding in its coverage of existing faculty and staff;
- 3) Educate the faculty and staff on the federal regulation that necessitates this agreement;
- 4) Emphasize that the agreement only confirms already existing practices and policies of the university.

CONCLUSION VI.

This article provides the rationale used in the development of a boilerplate "Intellectual Property Agreement." It identifies the terms and conditions that were selected for the agreement and those that were only considered.

Table 1

Selected Components Intellectual Property Agreements

Major Component	# of Agreements that include the <u>Component</u>
Compliance Requirements	18
Agreement Returned to:	ŧ.
Technology Transfer Office	11
Employment Office	3
Sponsored Projects Office	2
Departmental Office	1
Other	1
Inventions Made in the Course of:	+ 1
Sponsored Projects	18
Any Research Activity	11
Employment	11
Related to Employment	8
As a work-for-hire	2
Use of Institutional Resources	18
Documentation Required	18
Conflict of Interest Provisions	6
Effective Date	4
Binding On	5
Survival Clause	3
-	-
Total # of possible responses = 18	

Appendix A

Intellectual Property Assignment Agreement

I understand that the University has and will continue to enter into contracts and grants with government agencies, industrial corporations, and foundations for the performance of research, training and development activities, and that these sponsors impose and set forth certain obligations and requirements with respect to rights in patents, inventions, copyrightable materials, computer software, and other rights, defined below as "Intellectual Property."

In consideration of my continued employment by University or as a non-employee (i.e., visit, consultancy, etc.), the availability to me of opportunities to perform research including, but not limited to, sponsored research and/or to utilize University resources, I agree:

- That all inventions, copyrightable materials, computer software, semiconductor mask works, tangible research property and trademarks ("Intellectual Property") conceived, invented, authored, or reduced to practice by me in the course of my employment, with the use of University resources, or as a result of a work-for-hire shall belong to the University, and be subject to the provisions of the University Patent Policy dated and as amended from time to time; a copy of which may be found in my Department Head's office.
- To disclose promptly in writing through the Technology Transfer Office any such Intellectual Property, to assign all rights to such Intellectual Property to University or its designee for this purpose, or such other agency as the University may direct, to execute all necessary papers, and to cooperate fully (at no out-of-pocket cost to myself) with the University or such designee to enable the University to obtain, maintain, or enforce for itself or its designee, patents, copyrights, or other legal protection for such Intellectual Property.
- To make and maintain for University adequate and current written records of all such Intellectual Property, and to deliver to University upon request, copies of all written records referred to in this paragraph and paragraph 2 above as well as all related memoranda, notes, records, schedules, plans or other documents, made by, compiled by, delivered to, or manufactured, used, developed or investigated by University, which will at all times be the property of University.

NOTES

- Weidemier, "Ownership of University 1. Jean В. Inventions," Vol. IV:17, Journal of the Association of University Technology Managers, 1992.
- The American Heritage Dictionary of the English 2. Language, 1973, American Heritage Publishing Co., "agreement."
- 3. Ibid. at "assignment."
- Functions of the Patent and Trademark Office (Handout), 4. "Copyrights," I-4.
- 5. Supra note 4, "What is a Patent."
- 6. NCURA Intellectual Property Series, "Introduction to Patent and Patent Rights," Conditions for Patentability 11.
- 7. Howard W. Bremer, "University Technology Transfer: Where Have We Been? Where Are We Going?," Vol. 1 No. 1:7, Journal of the Association of University Technology Managers, 1989.
- 8. Massachusetts Institute of Technology, "Inventions and Proprietary Information Agreement."
- Supra note 3, "participation." 9.
- Supra note 4, "What is a Patent." 10.
- 11. Webster's 9th New Dictionary, 1986, Merriam-Webster Inc., Springfield, Mass.

Technology Transfer Office Performance Index

Albert E. Muir*

I. INTRODUCTION

In order to remain viable, providers of services must perform well and periodically render useful accounts of their services. For the university Technology Transfer Office (TTO), good performance means ever increasing monetary value of university-owned intellectual property. This property, or asset, is the faculty-produced invention. Inventions generate licenses and patents; that is, more highly valued assets. Licenses, patents, the financial values they embody, and the processes by which these values are achieved provide the material for evaluating TTO performance.

To evaluate TTO performance, this article proposes a Technology Transfer Office Performance Index (TTOP Index): a single, composite number characteristic of TTO associated outputs. The Index can be calculated periodically for comparative purposes, and used to spotlight strengths and weaknesses in services. Indexes as measures of performance are not uncommon. Consider the Index of Leading Economic Indicators, the Dow Industrial Average, or the Consumer Price Index,

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require automatic assignment of such rights as a condition of employment. However, the inventing faculty receive a fair portion of income produced by the technology, and might reacquire rights should the institution decide not to pursue the technology. The assignment ensures adequate resources for the exploration, exploitation and protection of property rights and income-generating potential, a responsibility best left to the institution and its TTO.

The Index takes account of both quantity, indicative of effort, and quality of service. It offers a ready means of assessing overall services, providing a performance evaluation that reflects how the TTO is doing relative to performance levels the office has been able to achieve in the past. As will become evident, few in technology transfer would doubt that the most favored direction for the performance measures, and consequently the TTOP Index, is upward.

II. DETERMINANTS OF THE TECHNOLOGY TRANSFER OFFICE PERFORMANCE INDEX

Five broad performance measures, or indicators, are utilized. These are listed below:

- (1) Invention Disclosures;
- (2) Comprehensive Evaluations of Inventions Performed by Licensing Candidates in Industry;
- (3) Income Generating and Industrial R&D Support Agreements;
- (4) Patentability Opinions, Patent Applications and Issued Patents;
- (5) Institutional Support for the TTO.

patenting possibilities.

Whether or not an invention is eventually licensed or patented, individualized attention to inventors will bring repeat disclosure, disclosures from new inventors trying to achieve rewards, and links between inventing faculty and the industrial community will become Accordingly, the measure of performance for the Invention Disclosures indicator is the ratio of total disclosures to total faculty, and the ratio of disclosures to number of total R & D projects. Important also is the number of departments participating. Therefore, the TTOP Index includes the relationship between disclosing total number departments and the departments.

(2) Comprehensive Evaluations of Inventions
Performed by Licensing Candidates in Industry.
Industrial liaison and creation of linkages
between inventing faculty and the industrial
R&D community constitutes what is typically
referred to as technology marketing. These
linkages, whether or not the direct result of TTO
liaison, ultimately determine the invention's fate
as a new product/process candidate.

For the reviewing company, the evaluation may result in the selection of an invention among competing inventions for licensing and commercial exploitation. Important in this process is the learning experience. The company becomes aware of the commercial and technological strengths and weaknesses of the evaluated technologies and gets to know the respective investigators as well as the capabilities of the originating institutions. It acquires an

obtain a full understanding of the invention. In marking the beginning of comprehensive technical discussions with the inventor, this Agreement is useful for assessing the number of direct industrial connections established by the TTO.

The Evaluation Agreement may be a Confidentiality Agreement, Testing Agreement, Screening Agreement, Materials Agreement, or Option Agreement. The relationship of these agreements to the number of companies contacted and number of inventions represents the effort expended on marketing and its quality. Campus visits by companies and visits by inventors to company sites also promote faculty inventor/industry ties, further enhancing opportunities for industrial R&D support and commercialization of technologies. These happenings are captured in the TTOP Index as desirable outcomes of marketing.

- (3) Income Generating and Industrial R&D Support
 Agreements. TTO has an obligation to the
 university and inventors who share in royalties to
 ensure best returns on licenses and other
 income-bearing agreements. This is accomplished
 by thorough
 - (a) Background preparation such as market analyses, valuations of the technology and determinations of technical and financial adequacy of licensee(s) prior to negotiations;

broadest satisfaction among the inventing faculty, vis-a-vis allocations for patentability opinions and patent applications, while achieving greatest value for its patent portfolio. Accordingly, effort for purposes of the TTOP Index is given by the relationship of patentability opinions and patent applications filed to invention disclosures. Number of options and licenses relative to issued patents, and issued patents relative to patent applications combine to define quality in the patenting process.

Institutional Support for the TTO. (5)University budget must respond to competing interests. Departments and divisions falter and die in this competition. The hardest times are those of fiscal austerity. At many institutions, the TTO venture is a relatively new undertaking, and therefore vulnerable when departments. competing with established Consequently, funding will be at even greater risk if considerations of value and good performance are not effectively presented to the top university administrators, and used to make the case for technology transfer.

Because of its impact on the budgeting process, the TTO services provided to enhance this indicator have implications for all the service categories indicated. This service might include comprehensive top-level management reports, and TTO advocation at Board of Directors' Meetings. Effectiveness in the representation of technology transfer interests and needs appears in the TTOP Index as a ratio of the TTO budget to the total university budget.

Table 1:

Calculation of
Technology Transfer Office Performance Index

Performance Indicator	Base	% of Base Average			
Relationships (Overall Totals)	Average	1991			
# Inventions/# Faculty	.15	115	130	150	
# Inventions/# R&D Projects	.10	100	80	110	
# Disclosing Depts./# Total Depts.	.25	105	100	115	
Average for Disclosures	·	107	103	125	
# Evaluation Agts/# Contacts	.05	120	110	125	
# Evaluation Agts/# Inventions	.85	140	120	130	
# Company Visits/# Eval. Agts.	.05	110	130	120	
Average for Evaluations		123	120	125	
# Options & Licenses/# Inventions	.20	90	105	120	
\$ Royalty/\$ University Budget	.30	110	95	115	
# Industrial R&D/# Total R&D	.45	105	120	125	
Average for Agreements		102	107	120	
# Pat. Opinions/# Inventions	.65	108	: 80	100	
# Pat. Application/# Inventions	.18	106	130	140	
# Options & Licenses/# Patents	.10	70	120	140	
# Patents/# Patent Applications	.75	100	120	140	
Average for Patenting Activity		96	113	130	
\$ TTO Budget/\$ University Budget	.12	85	112	115	
Average for Support		85	112	115	
TTOP Index	, ,,,,,,,	103	111	123	

data from institutions across the nation may be combined in a single National TTOP Index (NTI).

INSTRUCTIONS FOR CONTRIBUTORS

The Association of University Technology Managers (AUTM) welcomes contributions of original manuscripts to the AUTM Journal covering any aspect of the management of technology and intellectual property. Please submit manuscripts to Managing Editor, Ms. Diane C. Hoffman, 23 Perrine Path, Cranbury, NJ 08512.

All manuscripts, including those written at the invitation of the Editor, are subject to review by the Editorial Advisory Board or other reviewers. The final decision as to publication will be made by the Editor, and authors will be notified of the decision. Authors may retain title to the copyright of their articles; however, papers are published in the *Journal* with the understanding that they have neither appeared nor will be submitted elsewhere.

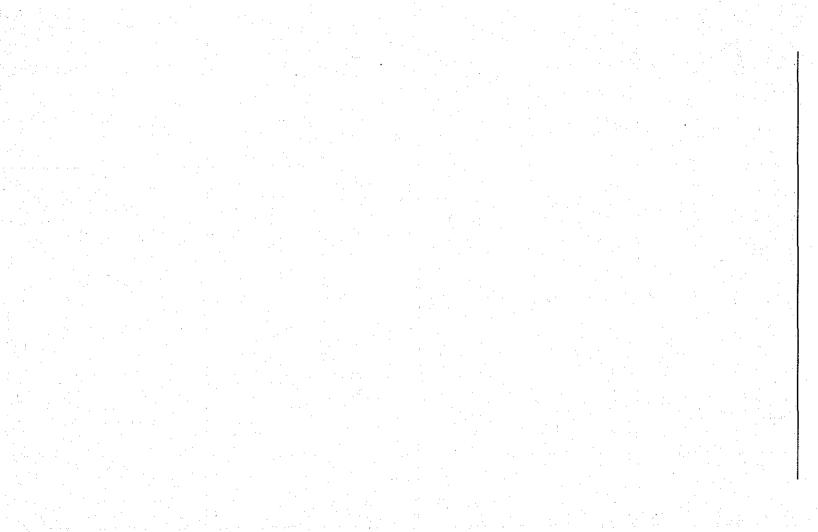
Please submit an original and two copies of your typewritten, double spaced, manuscript. The first page should contain the title, author's name(s), affiliation(s), address(es) and telephone number(s). An abstract of 100 words summarizing the paper's main points and a 50-word background statement about the author should also be included. Should your article be accepted for publication, you will be asked to provide a copy on diskette compatible with MS Word or WordPerfect software.

References should be numbered and listed at the end of the manuscript. Please avoid the use of footnotes. Tables and Figures must be numbered and identified as such, and should be provided in camera-ready format, ready for reproduction.

Letters commenting on the issues discussed in the published articles or on other matters of interest to technology managers are welcome, and will be considered for the "Letters to the Editor" section or forwarded to the author for reply, if applicable, at the discretion of the Editor.

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IV. CONCLUSION

The article identifies performance measures and ratios of general acceptability to technology transfer managers and the persons and institutions they serve. It incorporates these into a composite Index for evaluation purposes. By expressing the base year performance relationships as ratios, otherwise incomparable data is made comparable, and benefits attributable to institutional size alone are factored out. Furthermore, its use of averages in calculating the Index, holds the effects of abnormal fluctuations to a minimum.

The Index recognizes services rendered on all inventions. TTO is asked to maximize patents, royalty income and research support, as well as account for its role in using invention disclosures to create industrial links for faculty whose disclosed technologies show no immediate market interest. In its latter role, TTO seeks to enhance the number of market relevant inventions, and therefore licensable and patentable inventions produced in the future, by promoting awareness of industrial needs among faculty. This dual approach ensures maximization of invention disclosure potentialities in both the short-term and the long-run.

Finally, the methodology used for the Index is adaptable to the needs of practitioners not entirely satisfied with the particular formulation proposed. For example, some might argue that certain indicators are more important than others. In this regard, weights may be incorporated to recognize relative significance. Others might question the relevance of certain indicators, or components thereof. For these, the TTOP Index is amenable to substitutions, additions and deletions of indicators and/or ratios. Not only is the Index useful for single-office applications, it provides an approach for aggregate representations of TTO performance, in which

III. CALCULATING THE TTOP INDEX

Calculation of the TTOP Index is illustrated in Table 1. First a base period is proposed. Let this be the five years ending June 30, 1990. Then, ratios for the new years are calculated and expressed as percentages of the base period averages. Data for 1991 appears first, then for 1992, then for 1993. All the data is hypothetical.

In each year, an average is calculated for each indicator. This is obtained by simply adding the percentages reported and dividing by the number of such percentages; for example, the 107 indicated as the 1991 Average of Disclosures is arrived at as follows: [(115 + 100 + 105) = 320], then 320/3 = 107. The TTOP Index is obtained by averaging the averages, as follows for 1991: [(107 + 123 + 102 + 96 + 85) = 513], then 513/5 = 103.

The Index may be used to display total performance over time. Variations in the indicators too can be charted to show the areas of activity contributing to variations. Separate detailed analyses of the underlying causes of variation in the individual performance measures can then be conducted to help explain the observed overall annual differences in the Index.

In the data of Table 1, the 1991-92 Index gain is attributable to increases in the Agreements, Patenting, and Support of TTO indicators. Declines are reported for Disclosures and Evaluations. However, Disclosures contribute significantly to the growth of the Index in 1993, and a major portion of this is traceable to the inventions/faculty ratio. In this manner, variability is highlighted at increasing levels of detail, permitting a comprehensive appreciation of overall changes.

(b) Oversight and monitoring of executed technology transfer agreements to ensure optimal recovery of returns.

Greater numbers of such agreements relative to number of disclosures reflects TTO effort expended. This ratio is also indicative of participation among inventing faculty in actual and potential royalty streams. When viewing income generated, relative amount is an important consideration, and the TTOP Index includes it as a ratio of the total university budget.

The ability of the TTO to bring in industrial support directly and indirectly is included here as well, expressed as a ratio of industrial R&D to total R&D sponsored at the institution. As noted earlier, the recognition of institutional and faculty strengths brought about by TTO industrial liaison promote them as resources to be drawn upon in industrial new product/process research and development. Actual agreements reflect this recognition.

(4) Patentability Opinions, Patent Applications and Issued Patents. The criteria for a patent application are generally satisfied when a positive patentability opinion is accompanied by a licensing candidate willing to take a license. However, the latter is not always present. Also it may not be advisable to file even if the patentability opinion is positive. Know-how licenses (licenses not involving patents) are not uncommon.

With the above in mind, the task for the TTO is to allocate its spending to achieve the

appreciation of the originators' usefulness as potential partners in R&D and new product/process development. This latter point has significant implications for immediate and future relationships.

Inventors too. learn from this university/industry dialogue. **Typically** comprehensive corporate technology review includes extensive direct conversations between the inventing faculty and industrial counterparts. The inventor gets direct technical and market related feedback on business needs, acquiring an improved awareness of the market relevance of his/her technology and continuing research. He or she may achieve a relationship with the industrial community not unlike that achieved with scientific colleagues as a result publications in scientific journals and presentations at professional conferences. These outcomes bode well for the near term and long run in the potential they have for increasing the licenseability of research results; opportunities are lost to inventors and institutions whose inventions are not taken by the TTO beyond the immediate go/no go decision concerning licenseability, and patentability.

For the present indicator the concept of Evaluation Agreement is defined. A comprehensive discussion of proprietary information with third parties is generally not recommended unless an agreement is in place to protect confidentiality. The Evaluation Agreement serves this purpose and includes all agreements that protect the confidentiality of a technology while enabling a licensing candidate to receive information or samples in order to

Each performance indicator is discussed below, with its TTO services. Important relationships are also derived for the indicators and expressed as ratios. Fourteen such relationships are developed. In the concluding sections of the article, values for the indicators, based on the ratios, are calculated and averaged to arrive at the TTOP Index.

- (1) <u>Invention Disclosures</u>. University faculty are the developers, or suppliers of invention disclosures. Assuming they behave as suppliers, a demonstration by the TTO of remunerative services and reward will increase supply. Reward is return on licenses as royalty income, and/or appearance on an issued patent as a named inventor. Service is the effort expended to accomplish these ends. The TTO must exercise due diligence in these regards, and it may communicate this due diligence under the following headings.
 - (a) <u>Licensed technologies</u> communications with the inventors in regard to progress and status of licenses, income and patent rights;
 - (b) <u>Unlicensed active cases</u> communications with the inventors concerning progress toward commercialization agreement(s), reactions of licensing candidates, and patenting;
 - (c) <u>Inactive cases</u> communications with the inventors indicating reasons TTO has decided to relinquish rights, providing write-up of marketing efforts, names of companies contacted, reasons TTO failed to find an industrial sponsor, and

all of which exert powerful influences on decision makers.

Among the more popular proxies for TTO performance are patents and royalty earned. However, while these measures have a strong positive viewing in office output and figure importantly in the TTOP Index, university statistics across the nation show that most inventions are actually not patented. Also, most inventions do not generate royalty income. When particularly high levels of royalty income are reported, it is often the case that the amount is concentrated in a relatively few inventions.

The TTOP Index accounts for both licensed and yet-to-be licensed technologies. Patents might or might not be sought in both instances. In the former instance, prospects of income occur under the license. Regarding the latter, the TTO uses the disclosure to seek licensees, initiating communications between the respective faculty inventors and their scientific counterparts in industry.

Ideally the communications will lead to licenses. The dialogue creates awareness of industrial product and process needs in the field, providing an opportunity for market-driven modifications of inventions, thereby advancing licenseability. For interested faculty, the result might be research support for the disclosed technology, reorientations in research directions and possibly greater competitiveness in the industrial sponsored funds market. Other benefits include access to opportunities for consulting and university/industry collaborations, as well as a heightened visibility and regard for the institution as a resource in new product and process development.

The article assumes that invention ownership rights reside in the employing institution. Universities

- 12. Supra note 2, "release."
- 13. *Ibid.* at "waiver."
- 15. 10th at waiver.
- 14. *Ibid.* at "understanding."
- 15. 37 C.F.R. § 401.14 (f).
- 16. Supra note 1, at 13.

4.	Tha	at I	understand	and	accept	the	provisions	of	the
University's				policy	dated		,	and	as
amended fro	m time	to tir	ne.						

- 5. That I am now under no obligation to any person, organization or corporation with respect to any rights in Intellectual Property which are, or could reasonably be construed to be, in conflict with this Agreement, nor will I enter into an agreement which would create a conflict with this Agreement.
- 6. That I understand that this Agreement is part of the terms of my employment, covers the entire term of my employment (visit, consultancy, etc.), and that its obligations in regard to my activities shall continue after termination of my employment (visit, consultancy, etc.).

This Agreement replaces all previous agreements relating to the same or similar matters which I may have entered into with University. It may not be modified or terminated, in whole or in part, except in writing signed by an authorized representative of University. Discharge of my undertakings in this Agreement will be an obligation of my executors, administrators or other legal representatives or assignees.

Signed:			1.	Date:		
	(To include first	(To include first name in full)				
Position Title:						
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(When extracted from this article and formatted with standard margins, this agreement becomes a one-page document).

Signee/Principal Investigator Responsibilities

- a) I agree to ascertain and abide by all terms of sponsored agreements, especially as they relate to me.
- b) I agree to ensure each person, excluding clerical and non-technical workers, participating in research...for which..I am Principal Investigator, has signed..this agreement...
- c) I agree to deliver, when leaving the University, copies of all written records as well as all related memoranda, notes, records, schedules, plans or other documents, made by, compiled by, delivered to, or manufactured, used, developed or investigated by University, which will at all times be the property of University.
- d) I agree to keep informed of changes in intellectual property policy through revisions of the research policy manual or other announcements.
- e) I shall not disclose either during or subsequent to employment or association with University, any information, knowledge, or data of the University that I may receive or acquire during the course of employment or association with the University relating to the ideas, formulas, inventions, or other matters of a secret or confidential nature.
- f) I agree to submit early drafts of proposed articles, papers and abstracts to the Technology Office for review and possible action to protect patent rights.
- g) I agree to refrain from activities that may constitute or result in infringement of any patent, copyright, right of privacy, or other legal right.

The number of agreements that incorporated these provisions are as follows: a) 4; b) 4; c) 2; d) 1; e) 2; f) 1; and g) 1.

The boilerplate agreement is offered in Appendix A, and may be adapted in its entirety by technology managers or used as a starting point in the development of an intellectual property assignment agreement that, once edited, will be acceptable to the respective institution.

my appointment," and is binding on "...my executors, administrators, or other legal representatives or assignees."

13) Miscellaneous Clauses

The miscellaneous clauses selected from the agreements have been segmented into two subsections: intellectual property agreement concerns; and general contractual terms and conditions. Whereas the general contractual terms and conditions are incorporated into the boilerplate agreement, the intellectual property concerns are not.

a) Intellectual Property Agreement Concerns

- A statement regarding the inventor's right to request assignment in the event the university decides not to go forward with a patent application.
- A stated procedure for dispute resolution.
- A paragraph that expressly states the agreement is not applicable to an invention that qualifies fully under Labor Code 2870. (Applies only to the State of California).

b) General Contractual Terms and Conditions

- The agreement replaces all previous agreements.
 - The agreement may not be

principal investigator of a sponsored project that is in addition to the more generic terms of an intellectual property agreement. A complete list of these responsibilities is detailed in Table 2.

In drafting the standard intellectual property assignment agreement, our objectives were to: a) reduce the burden, when possible, on the signee; and b) keep the agreement to a minimum in both content and length. The responsibilities identified in Table 2 were not viewed as <u>essential</u> to an intellectual property agreement, and therefore, (with the exception of one) are not included in the boilerplate agreement.

These responsibilities, however, could prove useful to an institution facing a unique situation, and, therefore, should be viewed as possible solutions to a particular problem.

9) <u>Conflict of Interest Provisions</u>

Six of the agreements contained provisions for a possible conflict of interest. All of the agreements differed in the manner in which they dealt with: 1) an existing situation; 2) a potential future conflict; 3) means of correcting the situation; and 4) possible consequences.

None of the agreements, including the boilerplate agreement, contains all of the sentences listed below. Taken together, these statements address all four points identified in the above paragraph.

i) I am currently under no obligation to any person, organization or corporation in

institution's patent policy. This would depend on whether or not computer software developments are covered under the terms of the patent policy.

e) Amalgamation of Terms

After review of the agreements, the following paragraph was selected from the Massachusetts Institute of Technology "Inventions and Proprietary Information Agreement" for the boilerplate assignment paragraph:

"I agree ... to disclose promptly and to assign to [institution] all rights to all inventions, copyrightable materials, computer software, semiconductor mask works, tangible research property and trademarks ("Intellectual Property") conceived, invented, authored, or reduced to practice by me, either solely or jointly with others..."

The above paragraph offers the broadest claims, thus providing the greatest protection for an institution. In addition, these terms reflect the changing environment of technology transfer. The number of items to be protected by universities and the complexity of these items has been increasing for the past ten years. With this increase, the initial agreements designed to protect the rights to these kinds of intellectual property have become more complex. Agreements developed in the early '80s that provide only for patentable inventions and discoveries, or works produced under sponsored project, may no longer be sufficient for today's technology.

(Each of the paragraphs below represents terms and conditions from a different agreement.)

a) Inventions or Discoveries

The institution shall claim "...its right to acquire the title and control to such discoveries.." (a definition for "discoveries" was not provided, but inventions and discoveries are referred to throughout this document).

I agree "...to assign or confirm in writing ...all rights to any such invention or discovery if that is required by [the institution's] obligations to external sponsors of research or by the [institution's] policy."

b) Patentable Inventions or Discoveries

I will "disclose...all inventions, discoveries, or improvements, hereinafter called 'Inventions' which may be patentable..." I agree "...to assign to the University all patent rights in the U.S. or foreign countries to any and all said Inventions disclosed..."

"Patentable discoveries or inventions occasionally result from research or educational activities performed at a university ... the [institution] shall notify the inventor in writing whether or not it is the [institution's] intent to retain its interest and to acquire assignment of all ownership rights to the invention or discovery."

"...That any patentable invention or discovery which is conceived or first reduced to practice...shall belong to university." I agree "to The boilerplate agreement incorporates each condition noted in point b), and therefore, a *caveat* is provided.

Prior to implementation, legal counsel should be sought regarding the viability of applying these broad claims to existing faculty and staff. Ms. B. Jean Weidemier's article entitled, "Ownership of University Inventions," addresses this issue and offers some suggestions on how to prepare a "carefully-worded" agreement, so that an agreement signed later than the first day of employment can be of some assistance to a university in court, if necessary. These suggestions were reviewed and incorporated into the boilerplate agreement, where appropriate.

5) <u>Definition of Resources Used</u>

The language used to describe the "university's resources" varied among the agreements. Some examples include:

- the use of funds or facilities administered by university
- the use of university funds, facilities (excluding libraries), equipment, or materials
- significant use of funds or facilities (where significant is defined in a separate policy)

This is one instance where our boilerplate agreement is more general than those provided.

employer); and (once signed by all parties) is a properly executed and legally binding document.

2) <u>Compliance Requirements</u>

The following policies and guides represent a cumulative listing of those referenced in the agreements.

- · The university's Patent Policy
- Federal Policy
- The university's Royalty Income-sharing Policy
- · The institution's Research Policy Guide
- A Guide to policies relating to Intellectual Property

Those selected for the boilerplate agreement include the policies generic to all institutions: 1) the university's Patent Policy; and, 2) the university's royalty income-sharing policy. In addition, we added language to allow for future amendments to these policies.

3) Office to Which the Signed Agreement Should be Returned

The majority of agreements designated the Technology Transfer Office as the custodian of this form. Second to this office was the Employment Office.

In general, the office designated to receive this form should understand the significance of this agreement--that is, it meets a federal requirement and outlines the institution's rights to intellectual property. The title of an agreement should match the terms and conditions stated within it. To help determine which title might "best" represent the terms of an agreement, a few definitions are offered below. These definitions should be viewed as benchmarks, and can be modified as needed to fit a particular situation or institution.

Agreement. A properly executed and legally binding document.²

Assignment. The transfer of a claim, right, interest, or property.³

Copyright. Protection for the writings of an author against copying. Literary, dramatic, musical and artistic works are included within the protection of the copyright law. The copyright goes to the form of expression rather than to the subject matter of the writing.⁴

Invention. The subject matter of a patent.⁵ In order for an invention to be patentable it must meet the requirements cited in 35 USC 101, 102, and 103.⁶ Specifically:

- 35 U.S.C. Sect. 101. "Conditions for patentability; new and useful"
- 35 U.S.C. Sect. 102. "Conditions for patentability; novelty and loss of right to patent"
- 35 U.S.C. Sect. 103. "Conditions for patentability; non-obvious subject matter"

What is the "best" title for such an agreement?

These questions and more are pursued in this article.

II. THE PROBLEM

Princeton University conducted a survey in the Fall of 1992 to determine what universities have done or are doing with respect to the development of intellectual property assignment agreements. The University collected eighteen sample agreements, including a few samples of pertinent language incorporated in employee application forms. Few of the agreements, however, contained the same terms and conditions (see Table 1). They each incorporated language on compliance and documentation requirements, inventions made under sponsored projects and using the institution's resources, but there was little consistency among the other components. A small number of agreements, ranging from one to four, included specific provisions directed at either the employee signing the agreement and/or at a principal investigator (see Table 2).

III. THE SOLUTION

The authors have analyzed the agreements in great detail. The most common subject areas have been extracted from them and modified, as appropriate, to form a "boilerplate" Intellectual Property Assignment Agreement. This agreement is provided in Appendix A.

The major components identified in the agreements are discussed in the next section. Sample language is provided in each of these main categories, along with the rationale for including them in the boilerplate agreement.

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In addition, the Department should carefully heed the limitation set forth in 35USC 210(a):

"The Act creating this Chapter shall be construed to take precedence over any future Act unless that Act specifically cites this Act and provides that it shall take precedence over this Act."

in the interest of the public and of maintaining the competitiveness of the United States in a global economy.

In Conclusion

It must be remembered that the implementing regulations under Bayh-Dole and the Act itself were crafted, not in a vacuum, but as the result of experience gained under the Institutional Patent Agreements (IPAs) in the period starting in 1968, the date upon which the then Department of Health, Education and Welfare granted its first IPA, and from 1973 onward under the first IPA granted by the National Science Foundation. In effect, it means that the principles of Bayh-Dole have been working and working well, since long before the effective date of the Act itself.

Concerns were expressed in 1980, before Bayh-Dole was passed, and they are being expressed and evaluated again today. Will research agreements stifle the free exchange of knowledge, promote secrecy and distort academic priorities to conform with commercial aims? There was also speculation in 1980 that companies might exploit taxpayer funded research without providing an adequate return to the public. In her testimony before Congress in 1993, Dr. Healy put these concerns to rest. She said: "Fortunately there is little or no evidence that these adverse effects have materialized. In fact, the risks have been well worth taking: Highly productive university-industry relationships have blossomed since the passage of the Bayh-Dole Act. These relationships have yielded new products,

percentage rose to one in four at the end of the 1980's. Between 1980 and 1990, applications for patents on NIH-supported research increased by nearly 300% over the previous decade.

The cited statistics are meaningful not only from an economic perspective but in terms of products that have or exhibit the capability of saving lives or of improving the lives, safety, and health of the citizens of the United States and around the world. We believe that Bayh-Dole has been successful in facilitating the transfer of federally funded inventions from the university laboratory to the marketplace because it is based on fair and equitable principles that encourage university participation, balance the interests of both the academic and commercial sectors, and foster the university-industry partnerships that are essential to strengthening U.S. competitiveness.

Specific Regulatory Provisions

Three aspects of the regulations have drawn the special attention of the conveners of this meeting. First is the requirement for domestic manufacturing, which applies to an exclusive patent license for the United States. This provision is endorsed by COGR. Second is the preference for small business. This provision too is endorsed by COGR. Data show that it is being implemented to the extent that small business is interested and has the capability to succeed with the development necessary under specific licensing opportunities.

The third question addresses the "exceptional circumstances" authority, which allows the alteration of the standard clause of §401.14(a) in certain circumstances. Those circumstances are specifically spelled out in §401.3(a). Contrary to the language in the announcement of this meeting however, the "exceptional circumstances" authority does <u>not</u> include the right in the federal agency to limit the ownership rights of non-profit organizations or small businesses merely if the

interests of society that the patenting process and the freedom to publish the results of academic research are recognized as important contributions and that one activity does not proscribe the other. The university, as the titleholder of inventions and patents on those inventions, is in the best position to ensure that neither patenting nor publishing will be unnecessarily sacrificed one to the other. One should also keep in mind that under the disclosure inducement theory, which is the basic principle underlying our patent system, patenting ensures publication.

Benefits to Society

The Bayh-Dole Act has been successful because it not only benefits universities, but industry, especially small business, the government and the public.

University inventions usually stem from basic research and are, therefore, embryonic in nature and generally not product oriented. They require an industrial partner to secure the necessary development to bring them to the marketplace. The Bayh-Dole Act, which allows exclusive as well as non-exclusive licensing, provides the range of modalities needed by industry for commercialization purposes. Exclusive licenses provide the security industry needs in order to invest risk capital for further development of promising intellectual property.

In a 1989 survey (Mansfield), which included 76 major American firms in seven manufacturing industries, executives stated that a substantial portion of new products and processes introduced between 1975 and 1985 depended upon academic research and development. They explained that these products either could not have been developed (without substantial delay) in the absence of recent academic research or were developed with very substantial aid from recent academic research. (NSF: Science and Engineering Indicators-1989.) This is testimony to the ongoing cooperation between universities and industry, which is vital to U.S. international competitiveness

policy in 1981 and those principles and the Act itself, as amended by P.L. 98-620, along with the implementing regulations, remain a solid and reliable basis for the transfer of technology generated in whole or part from the expenditure of federal funds in 1993 and for the future.

Background and Principles of Bayh-Dole

Prior to passage of the Bayh-Dole Act, it was the policy of government agencies to take title to all inventions that were made in whole or part through the expenditure of federal funds. At the outset, one must presume that federal (tax) dollars are spent in support of research so that the public will ultimately benefit from the results of that research. The agencies, in embracing the "title" policy toward inventions made with federal funds, were singularly unsuccessful in transferring the technology represented by those inventions to the public for its benefit. The bureaucratic red tape that accompanied any attempt at innovation was simply too great a disincentive to any company seeking to license directly from the government. As a consequence, government agencies obtained and held patents on many inventions, but the technology represented by most of those inventions and patents was never transferred to the public because of the absence of a realistic technology transfer policy in the government agencies.

The Bayh-Dole Act recognized the shortcomings of the existing government patent policies and sought to correct them. It represented a recognition by Congress:

- (1) that imagination and creativity are truly a national resource;
- that the patent system is the vehicle which permits the delivery of that resource to the public;
- (3) that placing the stewardship of the results of basic research in the hands of the universities and small

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in an unbiased manner. Moreover, individuals at these institutions would be able to evaluate predictive results independently; thus providing a means to cross-validate the process model.

Although Phase II is not the focus of this paper, a cataloging method (albeit in primitive form) is proposed as a possible approach to the Phase II task. Using the linkage categories developed earlier in Section VI, a series of subclassifications are defined below:

PRIMARY PROCESS COMPONENT CLASSIFICATION STRUCTURE

- 1. <u>Intellectual Property Development</u>
 - 1.1 Patents
 - 1.2 Copyright
 - 1.3 Trademarks
 - 1.4 Others
- 2. Solicitation of Commercial Interest
 - 2.1 Direct Methods
 - 2.2 Inventions-to-License Databases
 - 2.3 Third Party Firms
 - 2.4 Regional Networks (1)
 - 2.5 Federal Labs
- 3. <u>License Preparation and Negotiation</u>
 - 3.1 University-Based
 - 3.2 Outsourcing Firms
- 4. Product Development / Manufacturing Integration
 - 4.1 Commercial Labs
 - 4.2 Government Facilities
 - 4.3 Technology Centers
 - 4.4 Licensee Internal
- 5. <u>Business Development / Marketing</u>
 - 5.1 Incubators
 - 5.2 Venture Capital Groups
 - 5.3 Regional SBDCs'
- (1) An example is the Texas Innovation Network (TINS), (ref. 8).

a planning tool. Assuming the tool's validity, it is then possible to expect its acceptance by the organizations, i.e., university, industry, or other that must ultimately benefit from its use. Although we have employed some degree of rigor to demonstrate process planning feasibility, certain areas may appear vague due to lack of physical experience. This is particularly true in the area of process component classification.

A framework for a more comprehensive approach to process planning by looking ahead to design and implement tasks is as follows:

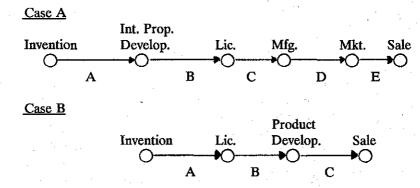
Phase I: Process Model Formulation

Phase II: Process Component Classification and Inventory

Phase III: Model Implementation (using database application)

Initial Phase I results are the content of this paper. Phase II and III planning is essential to the development of a database-driven process planning model. The task of cataloging the processes and their respective characteristics such as connectivity, cycle time, etc., is examined here as the next priority. There are an enormous number of programs, funding methods, public agencies, and commercial interfaces in existence. Such resources are in reasonable alignment in the area of life science-health related tech-transfer.

The linkage models chosen to demonstrate this application are given below. Note that in each case, a single path is selected. Nonetheless, in more rigorous planning, it is possible to evaluate alternate paths by assembling a network similar to the example given in Section VII. In doing so, it is possible to evaluate alternatives using a consistent analysis such as that demonstrated below.



The next step involves actual time scaling and development of path time estimation (t e). Using probable process paths identified in the previous models, the respective component path minimum, maximum, and most-probable times may be estimated from scaling information previously tabulated. The equations used to compute the minimum (t min) and maximum (t max) times based on the most likely (t prob) are developed as follows:

(Avg i) = average of (i) scaling factors in (jth) relevant path link parameter group.

(a, b, c, etc. subheading above)

IX. Process Planning Applications

Two case studies are developed in this section to illustrate the application of process planning and linkage classification.

The following descriptions provide overviews of university-owned inventions that are currently the subject of ongoing commercialization efforts.

Case	Invention	Source	Development Stage
A	Advance Composite Material	Small Lab.	Intermediate
В	Pattern Recognition Software	Large Research Center	Advanced

Following the planning method previously outlined, the process begins by assessing each case according to measurement criteria presented in Table 1. This process of scaling is subjective (1-10 = low-high, or difficult-easy), however, there is a fundamental need to perform this step to establish linkage times for commercialization path planning. The side-by-side comparison is intended to illustrate a range of application and not as a comparison of the relative merits of each invention.

An example of this side-by-side comparison begins on the following page.

Derito D. 2740500

attempt a statistical correlation of time lag (D) as a function of sales (S) and industry segment (Y).

$$D = A + BS + CY$$

Reported correlation was poor (r-squared=.3) due partly to a variation in company size in the sample data.

A third work by Razgaitis, (ref. 6) describes a method of technology valuation based on risk classification. A correlation between risk and the corresponding discount rate (k) in a net present value (NPV) calculation of intellectual property value is described. Using this model and the approximate ranges of (k) tabulated in the reference, it is possible to calculate the present and future value of an intellectual property (invention before and after commercialization) based on a prescribed time-to-market and a specified royalty income stream.

The value of these references is in the data that may be used to estimate process parameters required for the model developed in this study. In addition, they represent a source of encouragement to advocates of process planning since further quantitative assessments of tech-transfer processes are undoubtedly in progress, motivated partly by the existence of these works.

B) Use of Network-Based Process Planning

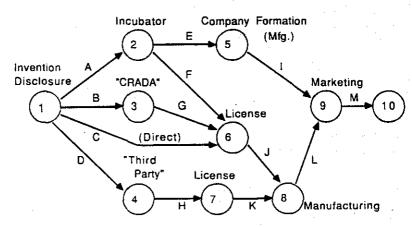
An illustration of process planning using the proposed model is described in this section. The following tabulation of alternative process path times is based on numerical results (ref. 3). Based on this demonstration, it is possible to compare candidate processes using calculated time-to-market estimates. In addition, the probability estimate of reaching the

VII. Process Component Parametric Classification

The next level of process definition requires some form of parametric classification that provides an inventory of alternative commercialization tools or paths, i.e., licensing, funding, development, marketing, etc. To establish a relevant measurement, the temporal parameter, time, is selected based on the widely recognized commercial priority of time-to-market. Using time measurement, it is possible to use a process network model based on Critical Path Method (CPM) principles as a method to compare alternate commercialization paths based on predicted time-to-market. An example of such a model is shown below:

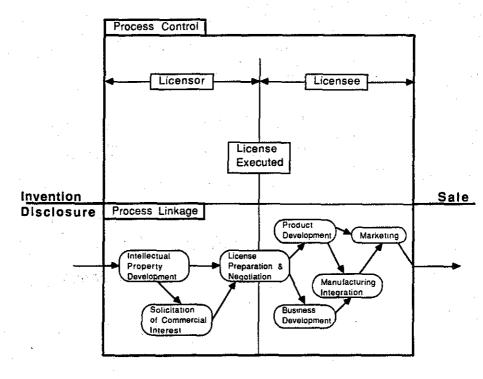
PROCESS NETWORK MODEL

(Alternative Technology Transfer Paths)



The nodes 1,2,3,etc. correspond to available alternative methods and the paths A,B,C,etc. are the respective time durations between nodes. Using time values corresponding to the minimum, maximum, and most-likely estimates for each path, it is possible to calculate the total (statistical) path time duration and corresponding probability of achieving that time within a prescribed tolerance. The numerical solution of this example is based on a CPM algorithm development (ref. 3).

Moving to a more detailed version of the process model, the components within the Transfer Process are identified in the figure below.



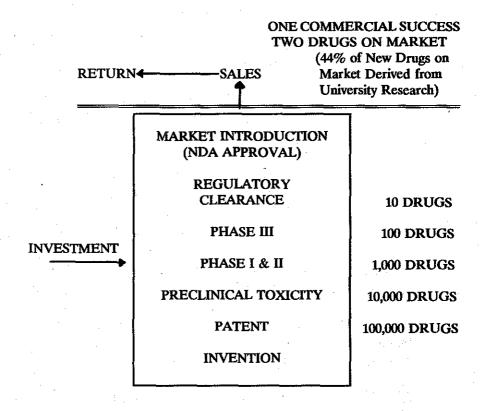
Commercialization Process - Linkage Classification/Development

The preceding illustrates a series of tech-transfer subprocesses each linked in some relation. "Linkage Classification/Development" is defined as the unique arrangement and interaction between process components occurring between invention disclosure and resulting sale. As shown in the figure 1, there are several subprocess characteristics each of which may be classified to form a basis for attribute scaling. Use of such a scaling method (measurement) provides a database formulation sufficient to inventory the myriad of process conditions in which tech-transfer takes place.

Specific classifications familiar to tech-transfer practitioners, such as engineering, medical, bio-tech, etc., are subsets of the above.

The following two diagrams illustrate the traditional steps associated with commercialization of respective field inventions. This comparison is intended to be the background for classification of process steps necessary for later model development.

INVENTION LIFE CYCLE - HEALTH SCIENCES



Consider, as an alternative the following possibility:

Using a process model/database implementation.....

Invention attribute and expected (desired) commercialization-result parametric data are input into the database. After several inquiry screens, the database execution delivers a selection of alternative plans compared parametrically as follows:

- Estimated Cost to Commercialize
- · Time to Market
- Cost/Risk Ranking
- · License Revenue Potential

B) Objectives

While it is recognized that the foregoing process planning database is, at best, fictitious, there exists at this time an immense population of tech-transfer resources, i.e., programs, agencies, funding, initiatives, hopes, and dreams that are virtually uncorrelated. Hence the priority appears to be cataloging and classification of resources. This and other tasks can be summarized in terms of development objectives as follows:

- 1) Use management planning practices to support decision making regarding invention commercialization.
- 2) Develop a planning method that can be used to provide quantitative measures sufficient to distinguish between

management planning principles, however, the author views a need to grapple with the problem, and therefore, lays a foundation for ongoing development. A brief literature search reveals that there is further reassuring interest in quantitative tech-transfer process. Several models of subprocesses and attempts to apply numerical characterization to such processes have been reported (refs. 4-6). The ensuing discussion of fundamentals is intended to establish a framework for justification, to address process-component definitions, and suggest possible methods of process attribute classification and scaling. Further discussion will address model formulation, measurement, planning application, and objective solution.

III. Observations

Some industry perspectives of university engineering-based invention commercialization are:

- 1) Limited familiarity with university research policies and practices.
- 2) Broadest possible range on invention characteristics.
- 3) Substantial difference between scope and subject of physical science research and perceived commercial need.
- 4) Demands on research faculty to publish work, often at the expense of intellectual property protection.
- 5) Invention evaluation limited to "paper" and, occasionally, a prototype device, a laboratory material sample, or a process demonstration.

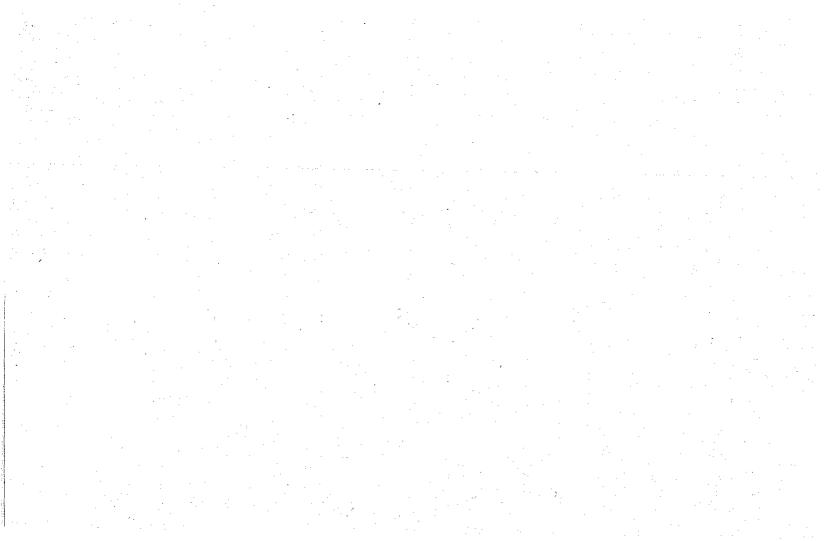
federal, local government, industry, private, or other, whose attributes combine in a funding-development-implementation relationship. A parametric resource database is proposed as a means to uniquely determine appropriate combinations. A technology-transfer process planning model is introduced as a means to estimate commercial success factors such as time-to-market and cost/risk ratio. In addition, the method is shown to be useful for evaluating alternate path linkages using a consistent objective means.

Two case studies are briefly reviewed each from a viewpoint of contrasting development linkages. Both are evolving programs with ongoing activity and involve university-based inventions with differing development approaches at the pre-licensing phase.

A concluding discussion compares regulatory processes associated with the life sciences with the undefined and largely unrecognizable phases of physical science invention development, the latter of which reduces commercial interest and seemingly reflects a higher risk to industry. The result supports development of a process planning model that defines industry recognizable development phases for such inventions similar to the life sciences field.

II. Statement of the Problem

Success in licensing inventions from university sources differs significantly when comparing life science and physical science areas. When measured in terms of royalty income, life science-based inventions represent a much larger income to universities compared to other disciplines (ref. 1). Several factors explain this difference, not the least of which is the industry that is served, health care. Although there is major national expenditure in this market that would explain the dollar



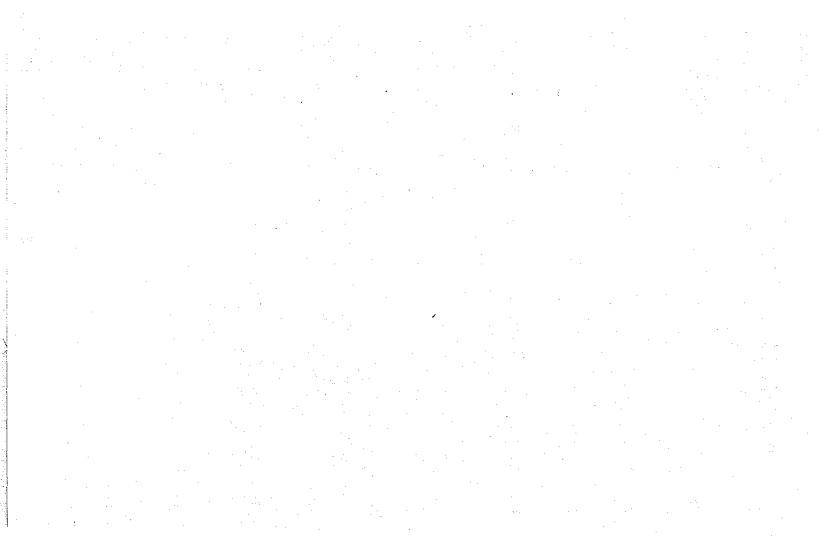
University Inventions," Princeton University surveyed fifty universities to determine what they have done to develop an intellectual property agreement for assignment of inventions to the institution. Diane C. Hoffman compiled the information and produced a "generic" Intellectual Property Assignment Agreement based on the samples received from eighteen universities. The resulting sample agreement is reproduced here in this article and may be useful to technology managers in their own institutions.

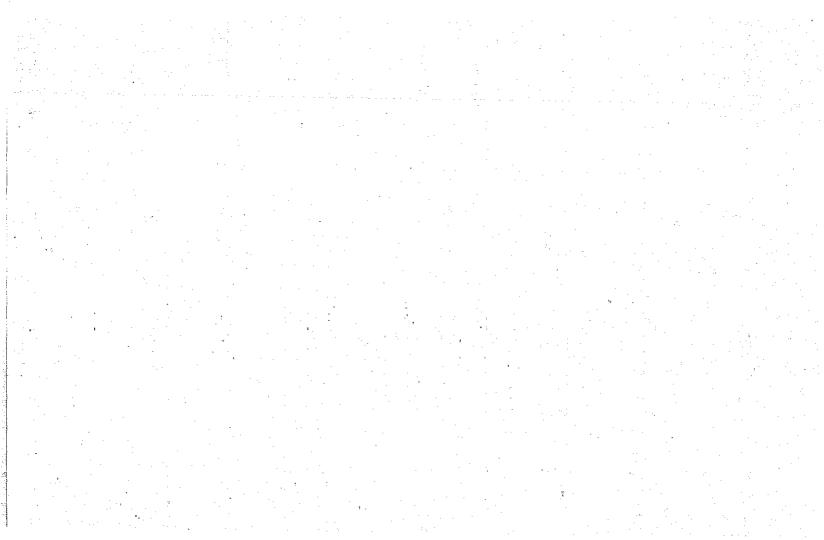
A common subject of discussion among technology managers is the need for a means of determining the success of our programs. Albert Muir proposes a quantitative method of measuring success by means of a "Technology Transfer Office Performance Index (TTOP Index)," which may be calculated periodically for easy comparison of results. This attempt to quantify the success of a program is timely, in light of the recent publication of the *AUTM Licensing Survey*, and we expect it will lead to further discussion on the subject of program evaluation.

With this volume, we are introducing a "Letters to the Editor" section. The Editorial Board of the AUTM Journal encourages letters and comments from its readers concerning issues discussed in published articles or on other matters of interest to colleagues in the field of technology management. Letters may be considered for the "Letters to the Editor" section or forwarded to the author for reply, if applicable, at the discretion of the Editor.

We thank those authors who took the time to write articles, and encourage our readers to submit original papers on topics of interest to professional technology managers and their colleagues in related fields. Those contemplating writing an article or a letter are asked to contact the Editor or the Managing Editor regarding content and review procedures.

Jean A. Mahoney, Editor December 1993





JOURNAL OF THE ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS

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