UNIVERSITY

LICENSING

Geoffrey G. Dellenbaugh

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UNIVERSITY LICENSING - AN INDUSTRY PERSPECTIVE

A. Introduction and Focus

- Licensing of IP focus on patents (other property includes copyrights, trademarks, character licensing)
- Licensing existing technology or technology created with research support from the licensee
- Pharmaceutical (university licensing important); other areas software.
- Mostly US (with ex-US nuggets)
- What makes university licensing different?
 - 1. Industry view: economics, confidentiality
 - 2. University view: advancement of knowledge, open disclosure
 - 3. Not like business-to-business licensing
 - 4. Offers good opportunities for win-win deals

B. University Licensing is BIG BUSINESS (AUTM 1995 Licensing Survey)

- Adds more than \$21 billion per year to our economy.
- Supports 180,000 jobs per year
- Over 1,600 new companies formed in 1980-1995 from university licensing
- More than 10,000 university licenses were signed in 1991-1995
- Examples of significant licenses:
 - 1. Cohen-Boyer (Stanford)
 - 2. Cisplatin (Michigan State)
 - 3. Gatorade (University of Florida)
 - 4. Synthetic Vitamin D (Wisconsin)

C. Where are we and how did we get here?

- University licensing before Bayh-Dole
 - 1. no effective licensing of government-sponsored inventions
 - 2. restrictive and varied government policies
 - 3. exclusive licenses disfavored
- US rules under Bayh-Dole (handout #1)
- Ex US rules (examples)
 - 1. Canada
 - 2. Sweden

D. Players and their Goals

- OTL Administrator: promote use of technology; satisfy faculty; income revenue
- Faculty: funding for research; publication; income
- Funding Agency: promote use of technology
- Industry: cost-efficient acquisition of technology

E. What can be licensed?

- product/process (the commercial item) e.g., Cisplatin
- tool (patented or unpatented) e.g., the leptin receptor
- bare patent (e.g., to unblock) e.g., university patent on new use of company's product

F. Licensing in Sponsored Research

- Mission conflict university seeking to promote research and also get revenue
- Option/License/Exclusive/Non-exclusive which is appropriate when?
- Financial Terms (When should/can they be agreed on?)
- Industry Diligence/Milestones
- Confidentiality/Publication
- Patenting
- Liability
- Other Issues

G. Model Agreements

Example: AUTM Technology Transfer Manual (Handout #2)

Benefits/Detriments of using model agreements

H. Points to Consider

University

- Do your homework
 - 1. know the value of what you are licensing
 - 2. know the industry and your potential licensee (previous dealings?)
- dealings?)
- Perseverance
- Triage your portfolio
- Contact sport
 - 1. knowing whom to call is key
 - 2. association meetings (AUTM; LES)

Industry

- Know university limits
 - 1. Bayh-Dole requirements
 - 2. State law requirements for state institutions
 - 3. Institutional policies
- Give value for value (and not just money)
- Contact sport position yourself to get called on the next big invention

I. Negotiating Strategy (with apologies to Lou Berneman; Handout #3)

- Needs and Wants
- Save the financial points for last

J. The Future

• Electronic matchmaking - Techex (Handout #4)

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Franklin Pierce Pres

The National Research Administrator's Resources Network

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The Bayh-Dole Act -- A Guide to the Law and Implementing Regulations

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Welcome

Welcome to the electronic version of The Council on Governmental Relations (COGR) publication The Bayh-Dole Act - A Guide to the Law and Implementing Regulations.

This publication is intended for the private use of research administrators.

The National Research Administrator's Resources Network makes no warrants or representations as to the accuracy or reliability of any information contained herein, nor as to its applicability or usefulness.

This document, which deals with the Bayh-Dole Act, is intended to inform the public about technology transfer at U.S. research universities. This guide has a compendium piece, entitled "University Technology Transfer--Questions and Answers". Although each document fulfills its own purpose, they complement each other. When taken together they present a primer on the subject.

The Council on Government Relations is an organization which includes among its members over 135 research intensive universities. This booklet does not claim to be a manual of university technology transfer and licensing activities. Rather, it illustrates the philosophy and processes currently practiced in the university community.

In preparing the material, the COGR Subcommittee on Technology Transfer drew on the assistance of many COGR universities. Their help is gratefully acknowledged. Reproduction for purposes of sale or

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Comments can be addressed to the on-line editor: killoren@rtto.psu.edu

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Abstract

Modern day technology transfer from universities to industry can be dated to the 1980 enactment of P.L. 96-517, the Bayh-Dole Act, and amendments included in P.L. 98-620, passed in 1984. This paper provides a summary of the legistlation and the implementing regulations, and describes some of the results to date.

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Introduction

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Technology transfer-- the transfer of research results from universities to the commercial sector--is closely linked to fundamental research activities in universities. The concept is said to have originated in the report, entitled "Science--The Endless Frontier" which Vannevar Bush wrote for the President of the U.S. in 1945. At that time, the success of the Manhattan Project had demonstrated the importance of university research to the national defense. Vannevar Bush, however, recognized the value of university research as a vehicle for enhancing the economy by increasing the flow of knowledge to be used by industry through support of basic science. His report became instrumental in providing a substantial and continuing increase in funding of research by the federal government. It stimulated the formation of the National Institutes of Health (NIH), the National Science Foundation (NSF), and the Office of Naval Research (ONR). Due to the success of these and other agencies, the funding of basic research is now considered a vital role of the federal government.

In the 1960s and 1970s, there was much study and debate surrounding federal patent policy, which eventually resulted in legislative activity. A major concern was the apparent inability of the federal government to transfer its technologies. There was no governmentwide policy regarding ownership of inventions made under federal funding and the diversity in policies among the various funding agencies resulted in a meager flow of government assisted inventions to the private sector. In 1980, the federal government had approximately 30,000 patents and only 5% of these led to new or improved products.

This problem was due, in large part, to restrictive government policies on licensing and a reluctance on the part of the agencies to permit rights to an invention to rest with the universities and other grantees/contractors that develop them [1] The government would not relinquish ownership of federally funded inventions to the inventing organization. Instead, it would make such invetions available by non-exclusive license to anyone who wanted to practice them.

As a result, an organization had no exclusive right to manufacture and sell a resulting product. Understandably, companies were not interested in the development of early stage inventions, if, when products finally were ready to reach the market, competitors could aquire a license and could then manufacture and sell the same products. Government remained unsuccessful in sttracting private industry to license government-owned patents, because what belongs to everyone, belongs to no one.

Late in 1980, legislatures and the administration finally decided that the public would be served best by a policy which encouraged the utilization of inventions produced under federal funding and which promoted the participation of universities and small businesses in development and commercialization process.

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Bayh-Dole Act and Related Legislation

The Bayh-Dole Act and subsequent amendments provide the basis for current university technology transfer practices. Thefederal patent and licensing policy was shaped by four events which occured between 1980 and 1985.

1. On December 12, 1980, P.L. 96-517, the Bayh-Dole Act was enacted into law. This statute contains several important provisions/2/:

• A uniform federal patent policy was established.

• Universities were encouraged to collaborate commercial concers to promote the utilization of inventions arising from federal funding.

• It was clearly stated that universities may elect to retain title to inventions developer through government funding.

• Universities must file patents on inventions they elect to own.

• The government retains a non-exclusive license to practice the invention throughout the world.

• The government retains march-in rights.

• Preference in licensing must be given to small businesses.

• Uniform guidelines for granting licenses were provided.

2. On February 10, 1982, the Office of Management and Budget issued policy guidance to federal agencies for implementing the Act. This guidance is known as OMB Circular A-124[3]. The government clarified the followinf provisions:

• Standard patent rights clauses for use in federal funding agreements.

• Reporting requirments for universities electing title.

• Special federal rights inventions.

3. On February 18, 1993, a Presidential Memorandum on "Government Patent Policy" was issued. It mandated broad application of the new government policy[4]. Two significant aspects are:

- Federal agencies were directed to extend the statutory terms beyond universities and nonprofit organizations to for-profit grantees/contractors as well.
- The Federal Acquisition Regulations (FAR) were amended. on March 30, 1984 to assure
- that all R&D agencies would implement the Bayh-Dole Act and the Presidential Memorandum.

4. On November 8, 1984, the original statute was amended. The new language, referred to as P.L. 98-620, provides further refinement[5]:

• The term limited on exclusive licenses was deleted.

• The Secretary of Commerce was substituted for the Comptroller General as the responsible party to determine "exceptional circumstances" when contractor rights might be overruled.

In summary, the Bayh-Dole statute and subsequent amendments created incentives for the government, universities, industry and the small business sector, and herein may lie the reason for its success. It was not until 1987, however, that all these provisions-- the Bayh-Dole Act, its statutory amendment, the OMB policy guidance and the Presidential Memorandum--were finalized in rulemaking, published by the Department of Commerce[6]. These rules specify the rights and obligations of all parties involved and constitute the operating manual of the modern technology transfer officer.

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Current Regulations

Procedures implementing legislative and executive patent and licensing policy regarding "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms" are codified at 37 CFR Part 401. The Department of Commerce is designated as the federal agency to promote commercialization and to assume responsibility to maintain these rules [7]. As technology transfer takes place, the following regulations must be observed:

- The provisions apply to all inventions concived or first actually reduced to practice in the performance of a project, whether fully or partially funded by a federal agency.
- The university has an obligation to disclose each new invention to the federal funding agency within two months after the inventor discloses it to the university.
- The decision whether or not to retain title to the invention must be made within two years after disclosing the invention to the agency. This time is shortened, if, due to publication of results, the one year U.S. statutory patent bar has been set in motion. Under those

circumstances, the university must make an election at least sixty days before the end of the statutory period.

 Upon election of title, the university must file a patent application within one year, or prior to the end of any statutory period in which valid patent protection can be obtained in the United States. The university must, within ten months of the U.S. filing, notify the agency whether it will file foreign applications. If the university does not intend to file, the agency may then file on its own behalf.

• If the university elects to retain title, the federal government is provided a non-exclusive, irrevocable, paid-up license to practice the nivention (or have it practiced on behalf of the U.S.) throughout the world.

- Any company that holds an exclusive license for sales in the United States, must substantially manufacture the product in the U.S. Waivers of this rule may be granted by the federal agency upon showing that reasonable but unsuccessful effforts had been made to find a company that would manufacture in the U.S.
- As they proceed to license an inventionm universities must give preference to a small business firm, provided the firm has the resources and capability for bringing the invention to practical application. However, if a large company has provided research support that led to the invention, that company should be awarded the license.
- Universities may not assign their rights to inventors to third parties, except to a patent management organization.
- Universities must share with the inventor any income collected on the invention. Any remaining income, after expenses, must be used to support scientific research or education.
- Agencies may decide, due to exceptional circumstances, that title is better vested in the federal agency. Such decision must be made up front and becomes part of the funding agreement with the university. The agency must file an "exceptional circumstance" determination with the Department of Commerce, which rules on its validity. These exceptional circumstances might pertain to national security of sensitive research projects/8/.
- In some circumstances, the government can require the university to grant a license to a third party. This might occur if the invention was not brought to practical use within a reasonable time, if health or safety issues arose, if public use of the invention was in jeopardy, or if other legal requirements were not satisfied/91.

Details of procedure and other rights and obligations not cited above, as well as further elucidation of those items discussed, can be found in 37 CFR 401 and 35 USC 200-212.

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Results

Has Bayh-Dole been effective in promoting technology transfer by universities? What measures can verify its effectiveness; and how much data are available? Some compelling data exist:

- In 1980, there were approximately 25-30 universities engaged in technology transfer: by 1992, there were 200. [10]
- Between 1974-1984, 84 universities applied for 4,105 patents (2,944 subsequently issued): in 1992 alone, 139 universities; recieved 1,557 patents. [11]
- During 1974-1984, 1,058 licenses were granted by universities; in the period of 1989-1990, 10,510 licenses wer granted. [12]
- In 1986, 112 universities reported licensing income of \$30 million, in the two year period of 1989 and 1990, 35 universities reported income of \$113 million. [13]
- According to the General Accounting Office, industrial support of university research has risen from 4% in 1980 to 7% in 1990. [14]
- A 1993 survey included 98 universities further illustrates the growing activity and success in university technology transfer for fiscal years 1991 and 1992. [15]

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Conclusions

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These data lead clearly to the conclusion that the Bayh-Dole Act has promoted a substantial increase in technology transfer from universities to industry, and ultimately to the public, as products become generally available. The Act provided a secure base to which universities could link some of their key research projects. Certainly of title to inventions made under federal funding proved to be most significant. While allowing commercialization, title also protects a researcher's rights to use and continue to build on a specific line of inquiry. Implementation of uniform patent and licensing procedures became the second indgredient for success. This combination of factors led to a tremendous boost in university technology transfer activities.

As Vannevar Bush foresaw, striking economic benefits to U.S. business have been a critical spinoff from this effort. University research and technology transfer has spawned the biotechnology industry and led to advances in the medical, engineering, chemical, computing and software industries, among others. Transfer of technologies has led to the creation of new companies, thousands of jobs, cutting-edge educational opportunities and spinoff to service industries.

As one example of this spinoff, the licensing income in 1989 and 1990 of over \$100 million for thirty-five universities can be extrapolated, on a 4% royalty bases, over \$2.5 billion in sales, supporting thousands of jobs. And, this is only part of the picture. One should also take into account the funds invested by industry in development and in supporting these sales. One must also recognize the investments in new start-up companies all across the U.S., from which products are forthcoming. Finally, one must remember hat U.S. universities have invested tens of millions of dollars since 1980 in developing their productive technology transfer infrastructure.

Perhaps, most importantly, one must acknowledge how technology transfer, facilitated by the Bayh-Dole Act, has improved our lives. New durgs, medical treatments, building materials, consumer products that started as an idea in a university research laboratory and now touch our lives daily. The Bayh-Dole Act permits universities to be effective in promoting technology transfer. We must all be mindful of the tenets from which the Act was derived, and must be vigilant in protecting the rights granted by the Act.

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Footnotes

[1] The term university(ies) as used in the text applies to all grantees/contractors.

[2] P.L. 96-517, Patent and Trademark Amendments of 1980. This law amended Title 35 USC, by adding Chapter 18, Section 200-212.

[3] Office of Management and Budget (OMB) Circular A-124 was subsequently codified at 37 CFR Part 401.

[4] The Presidential Memorandum was incorporated into the text of Office of Management and Budget (OMB) Circular A-124 on March 24, 1984.

[5] P.L. 98-620 amended Chapter 18, of Title 35 USC.

[6] Final rules were published on March 18, 1987 (52 FR 8552) and subsuquently codified at 37 CFR Part 401.1-401.16.

[7] The Secretary of Commerce delegated this authority under 35 USC 206 to the Assistant Secretary for Productivity, Technology and Innovation.

[8] Other Circumstances, not clearly elucidated in the regulations, may be invoked by the government. Further detail can be found in 37 CFR Part 401.3; general appeal mechanisms are found in Part 401.4.

[9] Such conditions including appropriate procedures, are described at 37 CFR Part 401.6.

[10] Informal survey of the Association of University Technology Managers (AUTM)

[11] Data for the 1989-1990 period is contained in a General Accounting Office (GAO) report, entitled "Patent Policy: Universities Research Efforts Under Public Law 96-517", dated April 1986.

[12] Data for the 1974-1984 period taken from General Accounting Office (GAO) report entitled "University Research Controlling Inappropriate Access to Federally Funded Research Results", dated May 1992.

[13] The source of the 1986 data is a General Accounting Office (GAO) report, entitled "R&D Funding: Foreign Sponsorship of U.S. University Research", dated March 1988, Appendix I.

[14] See reverence 12

[15] The AUTM Licensing Survey: Fiscal Years 1991 and 1992. Association of University Technology Managers, Inc., dated October 1993

Invention Disclosures: 1991-4848:1992-5,645; Total Patent Filings: 1991-1,922:1992-2,329; Licenses:1991-2,096:1992-2,632; Royalties Recieved: 1991-\$130M:1992\$171M

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HANDOUT #2

AUTM TECHNOLOGY TRANSFER PRACTICE MANUAL

VOLUMES I and II

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Inside Industry, University Licensing

Sensitivity to needs, wants of parties essential; focus initially on nonfinancial issues helps

lament often heard from U.S. industry licensing executives about their university' counterparts is, "They (university technology licensing officers) just don't understand business." Conversely, university licensing managers criticize their industry counterparts for not understanding (or even trying to understand) the mission and constraints of university technology transfer. University licensing managers also accuse their industry counterparts as being predatory and seeking to take unfair advantage of university technology licensing opportunities.

The purpose of this paper is to hance the dialog between univerty licensors and industry licensees. This paper reviews the basis of university licensing, decries the focus on financial considerations, suggests references for further study of valuation and pricing issues, delineates companies' and universities' needs in licensing embryonic university technologies, and proposes a negotiation strategy.

The traditional mission of universities is teaching, research and service.² Universities seek the advancement of knowledge for knowledge's sake. Universities are bastions of academic freedom and open discourse. Conversely, technologybased companies are interested in product-oriented research and development and the advancement of knowledge for profit. Companies strive for confidentiality and limited public discussion. Universities and industry do, however, share the

2. Increasingly, universities are also ecognizing ther role and responsibility as an engine for economic development. common goal of technology development and management — both are interested in the commercialization of new and useful technologies.³

Although the cultures, missions and objectives of businesses and universities differ, it is these very differences that permit the parties in technology transfer collaborations to structure win-win arrangements. The proposition here is that by focusing on the respective needs of the parties and their mutual goals and common intent, interactions between the parties will be less confrontational and more productive. This "work for what you need, negotiate for what you want," negotiating strategy proposes that the parties in any negotiation (but especially industry licensees and university licensors) address and resolve their nonfinancial needs and wants before negotiating financial terms.

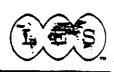
THE BASIS OF UNIVERSITY LICENSING

Why do universities seek to protect and license research results?⁴ United States Public Law 96-517, the Bayh-Dole Act (1980), and numerous subsequent executive orders (1981-1987) granted universities title to inventions conceived and developed with federal research funding. This policy was intended to facilitate technology transfer from the public to the private sector. Transferring

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HANDOUT #3

BY LOUIS P. BERNEMAN*



technology along the innovation chain from discoverers to developers and distributors was (and is) seen as promoting investment in product development, encouraging innovation, and assisting U.S. companies to compete globally, and stimulating economic growth.

Compliance with Bayh-Dole requires only few restrictions for universities granting licenses to industry:

• U.S. manufacture for the U.S. market.

Government march-in rights.

• Governmental nonexclusive, royalty-free license.⁵

Currently, Bayh-Dole and technology transfer are often discussed in economic development terms. Increasingly, science and technology are seen as vehicles for economic growth and global competitiveness, and universities are being recognized for their contribution to economic development.

Universities promote, protect and license research results for a variety of reasons, including:

• To facilitate technology/product development for the public good.

• To attract industrial research funding.

• To induce closer ties to industry.

To motivate and reward faculty.

• To provide employment opportunities for graduates and students.

• To foster economic development.

• To generate income.

Income generation from fees, royalties, and equity is usually near the bottom of any list of reasons univer-

^{1. &}quot;University" refers to universities, notfor-profit research institutions and hospitals.

^{3. &}quot;Major Issues/Conflicts in University-Industry Spongored Research/Licensing Agreements" by Jay Simon, Chief Attorney, Excon Research and Engineering Company, Licensing Executives Society (USA & Canada), Technology Transfer Seminar, April 21, 1994, New York, New York.

^{4.} Licensing Research Results is the title and a phrase used by Jon Sandelin, les Nouvelles, Volume XXVIII Number 3, September, 1993, p. 127. In reference to universities' activities in licensing their technologies.

^{*}Director, Licensing and Business Development, Virginia's Center for Innovative Technology, Herndon, Virginia; theme and text developed for the LES (USA & Canada) Industry/University (E-2) Committee and as a chapter for the Association of University Technology Transfer Manual, Volume III.

sities license technology. Few universities have hit "financial home runs" from technology licenses. Even those universities most successful in technology licensing enjoy or project income from these activities that account for only a few percentage points of their institutional research budgets.

FOCUS ON FINANCIAL CON-SIDERATIONS

Given that licensing activities are designed to promote and support the university mission and are specifically intended to facilitate technology development for the public good, why are university licensors so preoccupied with the financial terms of licenses? Be honest. In planning for negotiations don't you think first and most about royalty rates, fees and other financial considerations?

Increasingly, university technology licensing officers are expected to be financially self-sufficient. In these situations, outside patent legal costs, personnel, office expenses and overhead must be financed from royalty and fee payments.⁶ Continuing budgetary pressures, especially on public institutions, is likely to aggravate this situation. University licensing managers confronted with this reality are advised to share this constraint with their industry counterparts.

Some university licensors are apprehensive that colleagues will chastise, criticize and otherwise question the financial terms of negotiated agreements. This seems to be true even in those situations where transfer or commercialization of the technology is the priority, not income. University licensors want to strike the best deal for their institutions and inventors. But, what is the best deal? If the objectives and priorities of licensing research results are as enumerated above, then income generation should be a relatively low priority in negotiating agreements. In the real world, though, failure to negotiate fair and reasonable financial terms - even if all other institutional objectives are met -- will expose the university licensing manager to ridicule and possibly worse. (Increasingly, though, licensing managers are realizing that establishing relationships with industry and obtaining research support is in the best interests of both parties.)

In addition to technology licensing offices being financially selfsufficient, university administrators are very much concerned with keeping faculty happy. Faculty satisfaction — and the corollary, minimizing faculty complaints - is of major importance to university licensors. Faculty have always been 'greedy'' in their interactions with industry for all the right reasons. Faculty have sought to obtain industry financial support for their laboratories, students, expansion of the research programs, etc. In this context and from the perspective of a university licensors, greed is good. Recently, university technology managers are being confronted with a different type of faculty greed - greed for personal gain. Faculty are increasingly seeking to review terms of license agreements to assure that their personal financial interests are being served. Repercussions from this type of greed may be significant.

Industry licensing executives approach each technology acquisition opportunity knowing management will scrutinize the numbers. After all the due diligence related to technical merit, commercial potential, strategic fit and protectability, profit analysis will be the key criterion in the licensing decision. Industry strategic planning, business development and technology acquisition executives base licensing decisions on ROI (return on investment). Technical merit, commercial potential, protectability and strategic fit are necessary, but insufficient. The ultimate hurdle for every industry-university license is

financial.

Companies need reasonable financial terms in acquiring technologies from universities. Businesses survive and thrive on profitability. Profits are their reason d'etre. University licensing managers must recognize this fact, accept it, plan for it and use it in the preparation and conduct of licensing negotiations.

VALUATION AND PRICING

Increasingly, industry licensing executives recognize that universities are due a fair and reasonable financial return for use of university technologies. Companies recognize that fees and royalties are a cost of doing business in obtaining the rights to technology.

Experience indicates that very few industry-university licenses are not consummated solely because of financial differences. When there are insurmountable differences, they appear to be of this general nature:

A large chemical company sought to license a polypropylene and liquid crystal polymers blending and mixing technology. This technology, then early in patent prosecution, has broad application for the manufacture and use of high-performance polymer blends for automotive, aerospace and other transportation vehicle parts as well as biomedical devices. The chemical company wanted an irrevocable. exclusive, worldwide, royalty-free license. They offered to pay a onetime license fee. The university was willing to grant the license on this basis with a due-diligence provision to commercialize the technology, two years of sponsored research funding at \$125,000 per year and a "significant" license issue fee. Perceptions of "significant," however, were an order of magnitude different, the company offering \$35,000 and the university wanting much more.

Valuation and pricing is a topic of considerable attention in all technology transfer discussions. At AUTM and LES meetings, this area is a common presentation topic. However, it is beyond the scope of this paper. Readers are encouraged



^{5. &}quot;Issues in University Licensing." Licensing Executives Society, Annual Meeting, San Francisco, CA, October, 1993, Lita Nelsen, Director, Technology Licensing Office, <u>MIT</u>.

fice. MIT. 6. The requirement for financial selfsufficiency also pressures licensing officers to invest in and file patent applications only on technologies most likely to be licensable. Thus, early-stage technologies and those of lesser commercial significance due to market size or industry's lack of interest in new technology may go unprotected.

to review the AUTM Technology Transfer Practice Manual, Volume II, Part 7 for a comprehensive discussion of these issues.

• Chapter 3, "Royalties, Valuation Financial Considerations" by Marcia Rorke, Edmund Astolfi, B.I. (Woody) Friedlander and Teri Willey.

• Chapter 4, "Pricing the Intellectual Property Rights to Early-Stage Technologies: A Primer of Basic Tools and Considerations" by Richard Razagaitis.

• Chapter 5, "Finding Comparable Licensing Terms" by Ashley Stevens.

NEEDS AND WANTS

This paper proposes a negotiating strategy where the nonfinancial needs of the parties are addressed and resolved before any discussion of financial terms. In planning for negotiations, the parties are advised to analyze, specify and prioritize their needs and wants.

University licensors are advised to consider the needs and wants of potential licensees to make the relationship and license attractive. University research results generally describe technology opportunities that are embryonic. The practical utility of these opportunities is not established, and introduction to the marketplace will require significant investment and risk. This need for more R&D is consistent with the university's reasons for licensing. Collaborations can be structured to meet each party's needs.

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With exceptions for institutional policies and practices, generally, Universities Need:

• Assurances that the licensed technology will be commercialized for the public good. Due diligence is vital. Universities will want the right to terminate or reorganize or relicense technology that is not being diligently developed. Universities will want to retain ownership of the licensed technology and the recognition that the contract is a license and not a sale or assignment.

 Incentives and recognition for faculty researchers to encourage their cooperation in the technology transfer process and to encourage their submission of additional invention disclosures.

• Academic freedom to use the technology in the conduct of research, publication of research results and collaborations with colleagues.

• Indemnification by licensees against liabilities arising from the use of the licensed technology.

• Reimbursement of patent and licensing costs.

Sponsored research funding.

• Income (fees, royalties and equity).

Though their cultures, missions, goals, policies and technology licensing practices differ, companies' needs are generally predictable. There are differences, however, in the needs of large, mature companies and those of venture financed start-ups that should be considered. These include the lack of cash available for up-front fees, university or research ownership (equity), and experience in licensing. Companies' needs include:

• Financial terms that do not significantly impinge on profitability. Companies require a sufficient ROI to meet managements' hurdle rates and stakeholder value requirements.

• Sufficient control of the technology and flexibility of action to commercialize. In many cases, companies will want or need exclusivity.

Confidentiality to protect their investment.

• Rights to improvements.

• Know-how to practice the licensed technology.

University licensing managers seek to address companies' needs while protecting the universities' interests. For example:

• Companies can be granted exclusivity — a potential danger to the university — by including due diligence commercialization milestones to maintain exclusivity. The risk of exclusivity can be mitigated further by fields-of-use and time restrictions. In any event, the university will need to be assured that the technology will be commercialized for the public good and the company will require that it controls the technology and has flexibility with respect to development. Though confidentiality is antithetical in many cases to the mission of universities, companies can be granted limited periods of confidentiality to assure that they have time to protect intellectual property rights and gain advantage over nonlicensee competitors. Provisions of opportunities to preview research results, manuscripts, presentations, etc. prior to dissemination are often adequate (though not preferable to either party).

 Universities are loathe to grant broad rights to improvements that may restrict or inhibit university researchers' future lines of research or funding. The parties can resolve these differences and meet their needs by limiting rights to improvements to those dominated by the licensed technology that are conceived or developed in a research program funded by the licensee. "Dominated" language may be too restrictive in certain cases, however, and alternative compromise language may be required.

• Naked patent rights alone seldom are sufficient for effective technology transfer. Research contracts that accompany license agreements can facilitate the transfer of technology and provide funds for faculty and students to help further develop the technology.

Resolving these and other differences requires flexibility and a focus on intent — the commercialization of new and useful technologies.

NEGOTIATING FINANCIAL TERMS

Failure to address the needs and considerations discussed above early in the negotiating process is likely to be counterproductive. As soon as the parties sense they are likely to reach agreement on these needs, however, they will be anxious to address financial terms.

A direct approach in negotiating financial terms is recommended. Directness can be both more productive in the short-term in consummating the license and in the long-term in establishing/maintaining the relationship. The assumption behind this direct approach is

that university licensing managers are not likely to possess an in-depth knowledge of the characteristics and profitability of any particular industry. Therefore, attempts to use cost, income or risk or other value or pricing models or formulae are not likely to yield useful information. In addition, these models or formulae may have limited utility for embryonic technologies for markets or products that neither exist nor are well-defined.

The direct approach requires the licensee to assist the university licensing manager to understand the economics of the market and create a 5-10 year product revenue forecast. This forecast would include estimates of market size. growth assumptions, market share,

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and gross margins. Using these agreed upon assumptions, the parties can then discuss the relative contribution of the licensed technology to the product, revenues and profitability. These discussions often reveal the financial needs (hurdle rates, gross margins) of the licensee and establish a basis for pricing and the setting of fees, rovalties, due diligence requirements and other financial considerations.

SUMMARY

Negotiating industry-university technology licenses should be based on the intent of the parties - the commercialization of new and useful technologies. Universities want

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to facilitate development of the technology for the public good, attract industrial sponsorship of research, induce closer ties to industry, motivate and reward faculty, foster economic development, provide opportunities for students and graduates and generate income. In achieving these goals, however, universities have certain constraints and needs. Likewise, companies too have wants and needs.

An understanding of these respective needs and wants is essential. Planning and structuring the negotiating process to initially focus on nonfinancial considerations as a prelude to negotiating financial terms will facilitate consummation of the license and the long-term relationship.

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HANDOUT #4

technology**exchange**

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About Tech Ex

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What Is Tech Ex How It Works Advantages Background Obligations

What Is Tech Ex

Technology Exchange facilitates the marketing of new technologies from academic technology transfer offices to appropriate commercial developers. It is currently free to all users.

Imagine a one step technology marketing process that is rapid, thorough and accurately targeted. For universities, a server picks your your new technology descriptions daily, sends them to interested corporate representatives, and returns you a recipient list. For companies, you are immediately notified of any new technology matching your self described interests without receiving irrelevant ones. This is Technology Exchange! Gone are the need for universities to generate recipient lists for new technologies, and the need for companies to search innumerable sources for licensing opportunities.

This resource is an internet based, push/pull technology service with universities at one end and life science companies at the other. It revolutionizes the marketing process with a more rapid, thorough and targeted approach that will replace current, time-intensive marketing practices and become the single source for new technologies.

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How It Works

Technology Exchange is straightforward and powerful. At one end, universities provide Technology Exchange with non-confidential descriptions of their new technologies, which are uploaded into our database (the Pull). On the other end, corporate licensing professionals establish accounts with Technology Exchange where they can register searches based on their interests. Each day, our server picks up the new university technologies and sends out the descriptions to those licensing professionals whose searches match (the Push). In addition, Technology Exchange automatically notifies a university whenever a corporate search matches one of its new technologies (another Push). All future interactions concerning the technology occur directly between the university and the company.

The Technology Exchange database retains all technologies it picks up and can be searched by companies at any time. Our database responds actively to company searching so that whenever a company views a complete technology description, the university is notified (there is no notification when titles are returned by a search - only when the full description is viewed).

returned by a search - only when the full description is viewed).

The nuts and bolts of our service are described on the Technical Details page.

Contents

Advantages

- Not a Passive Search List. Passive databases do not return information to universities about the searches performed on their technologies. These lists are frequently used by universities as a last resort, which means that their quality of their listings can vary.
- Active. On a daily basis, our server automatically pulls in technology descriptions from universities and pushes them out to interested corporate licensing professionals.
- Accurately Targeted. Corporate licensing professionals control what they receive by maintaining their own searches, which they can change and fine-tune as desired, and universities receive a list of recipients of their technology descriptions.
- Reduces Marketing Effort. Technology Exchange reduces the academic and corporate marketing process to a single step for the accurate and thorough distribution of new technologies. Technology Exchange is desgined to create no "extra work" to use it.
- Insider's Service. Membership is restricted to legitmate research institutions and companies capable of commercially developing early stage technologies. Whether seeking new technology or a commercial partner, our up to date system will put you in touch with just the right people.

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- Single Source. Technology Exchange's unique advantages for universities and companies will make it the single source for new technology licensing opportunities, greatly simplifying the marketing process.
- munoung process.
- Free. The service is currently free.

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Background

Technology Exchange was conceived at the Yale University Office of Cooperative Research. We were frustrated with the inefficiencies of distributing new technologies to appropriate companies, and recognized that companies often had similar frustrations locating technologies of interest among the vast number of university opportunities. We recognized that universities and corporate partners had a common interest in improving this interaction and set out to design a better system.

We reviewed numerous "technology-matching" services and found that they all shared common shortcomings: most are passive search lists that do not actively target appropriate recipients, and none provide feedback to universities about who has shown interest in their technologies. Consequently, universities have found little incentive to use these services, and companies do not see them as a primary source of new technology. Few if any licensing deals have originated from these services. Yale created Technology Exchange to take advantage of the shared goal of efficient, directed information exchange between universities seeking commercial partners and companies seeking commercializable technologies. Technology Exchange brings technology marketing into the twenty-first century by applying the power of Push Technology - through a combination of email, intelligent databases, interactive websites - to the growing field of university/corporate technology transfer.

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Obligations

FOR UNIVERSITIES

We ask only that universities use this service in a responsible manner and provide Technology Exchange with genuine and well developed novel technology descriptions.

FOR COMPANIES

There are no initial obligations. At some point in the future, companies will pay an annual subscription fee for unlimited use of the service. Technology Exchange does not take a cut of licensing revenues.

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 - Setting Up a Profile or Search
 - Format Options for Delivering Descriptions

FOR UNIVERSITIES

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The Technology Descriptions

Technology descriptions are the currency of Technology Exchange. The technical details of how technology descriptions are structured, formatted, and made available to Technology Exchange are outlined below. It is not as difficult as it might seem. Tech Ex stores each technology description as 7 separate fields in our database, as shown below in the <u>Structure of Technology Descriptions</u> section. To upload your technologies, we need to put your information into these fields. There a several ways to accomplish this interaction, which are outlined below in the <u>Making Technology Description Available to Tech Ex</u> section. If you have any questions after reading the following sections <u>contact us</u>.

Contents

Structure of the Technology Descriptions

Tech Ex saves technologies in its database in the following fields:

- 1. Date of Disclosure In US format (mm/dd/yy).
- 2. University's ID number for the technology Up to 10 characters.
- 3. Title of Technology
- 4. **Text** Complete description of the technology including relevent patent publications anything you want a prospective licensee to know.
- 5. Keywords Include any important keywords from the list of keywords provided as well as free keywords as needed (see keywords below).
- 6. Contact Email Email of University contact for the invention. The "reply to" setting on the email notification of a technology sent to a prospective licensee will be set to this email address, making it easy for the recipient to reply directly to the University contact.
- 7. **Redistribute** In the unlikely event that you have significantly changed a description and would like it redistributed to those people who have already seen it, this field allows you to specify the date on which you would like the information redistributed. If no redistribution is desired leave it blank.

Fields 1 through 6 cannot be blank, while field 7 can. Field 7 should be blank nearly all the time. We strongly discourage universities from redistributing technology descriptions to recipients who have already seen them unless there have been very significant changes.

<u>Contents</u>

Making Technology Descriptions Available to Tech Ex

There are several ways we can arrange to have your descriptions uploaded. They can be divided into two general approaches: 1) you deliver your technologies to us, or 2) we pick them up from you. The following are the different ways to upload technologies, with a reference to the required format. If you have another approach you would like to use, contact us and we can very likely make it work:

Delivering technologies to us

- Upload directly to Tech Ex via our Invention Submission Form . We have specially designed the Invention Submission Form to make it easy for you to submit non-confidential technology descriptions directly to Tech Ex and to edit and manage existing descriptions in the Tech Ex database. The form handles all formatting and provides pop-up menus of keywords. Using this form you can list, sort, add, delete and generally manage your technology descriptions. The form employs Javascript (it requires Netscape 3.0, Internet Explorer 4.0 or later versions) which allows for real time interaction. Printouts from this page are customizable (i.e. can include university logo and contact information at the top), so it can serve as your primary database for storing technology descriptions.
- Email format 1.
- FTP to Tech Ex site format 1.

Tech Ex picks up technologies from you

- Password access to your database containing the technology descriptions format 2.
- HTML off of your website format 2.
- FTP to your site <u>format1</u>.

Formats:

- These files must contain the 7 fields (shown above in the <u>Structure of Technology Descriptions</u> section) in ascii comma delimited format -- all fields in quotes separated by commas with records separated by paragraphs.
- 2. On your web page or your database, you need to generate the 7 fields shown above in the <u>Structure of Technology Descriptions</u> section, and give Tech Ex access to them.

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Adding Keywords to Technology Descriptions

The use of consistent keywords is essential to this service. Accurate and thorough distribution of technologies cannot be assured without it. We provide a <u>list of keywords</u> divided into 3 categories:

- Industries 8 life science industries. At least one keyword from this category must be included with every technology description.
- Disease Areas These are very broad disease areas taken from the Merck Manual. Specific diseases are not listed here (aside from cancer). If you have a technology related to a specific disease such as Lupus, be certain to include the general disease area, in this case immune, as well as listing the specific disease as a free keyword.
- Applications This is a collection of terms which do not fall into the above to categories. If you do not see a keyword listed here which covers your an important application of your technology,
- add it as a free keyword.
- Free Keywords Keywords which you add by hand which do not appear in the above categories.

You can pick as many keywords from as many categories as you like to describe your technology. Note that at least one keyword from the "Industries" category is mandatory.

You can also add keywords which are not listed in any category, called free keywords. The words we have listed are not exhaustive, such a list would be overwhelming, but they are general and therefore important to use. However, it is likely there will be free keywords that you will want to include as well. For example, if you have a hair regeneration invention you would want to select the general terms "therapeutic" and "dermatologic", but you would also want to say "hair" as a free keyword since it is not on the list. It is crucial that you think in terms of using the best keywords from the list and then add free keywords as appropriate.

If there are any general terms you feel should be on the list which are not, please send us <u>feedback</u>. If you have questions be sure to <u>contact us</u>.

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How To Remove A Technology

- If you are delivering to Tech Ex (see above) then log onto your account and delete the technology from your list.
- If we are picking it up from you then simply remove the technology description from the place where technologies are picked up. Tech Ex will update your list to reflect the change.

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FOR COMPANIES

Profiles and Searches

We have designed a flexible process to help you accurately and thoroughly target the technologies you want. This section describes two ways to identify technologies of interest, the search process, and your options for having technology descriptions delivered. Note that we have also taken steps to ensure the security of your searches (see the <u>security</u> page).

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Identifying Relevant Technologies

There are two ways to identify technologies of interest to your company, Registered Profiles and One-Time Searches:

- **Registered Profile** You create one or more registered profiles which are stored on our server. These profiles are confidential, secure and can be modified at any time. Each time a new university technology is submitted to Tech Ex it is compared against your profile(s). Matches are immediately sent to you in your choice of formats (see Format Options for Delivering Descriptions below). This is the best way to be notified of emering technologies in your area of interest.
- One-Time Search You search the current contents of the database. You can set how far back in time you want the search to look. Hits are returned as a list of titles with hyperlinks to the full description. Anytime you look at the full description of a technology, the university from which it originated will be notified that you have received the description. Your search criteria can be named, saved and recalled at a later date.

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Creating Profiles and Searches

The Tech Ex search criteria used to match your profiles with incoming technologies, and in your one-time searches, are more flexible and friendly than typical Boolean search terms. We offer two comments about designing profiles and searching:

- Simple and General. Design your profiles to be as simple and general as possible. You can set up as many profiles as you want, naming each one to distinguish them. Complicated or overly restrictive profiles may miss technologies that you would be interested in but which do not fall within your very specific focus.
- Information Overload? There is little danger of your receiving more hits than you can handle. Remember, profiles are only matched against new inventions. Based on recent AUTM data, we estimate a total of 6 new descriptions per day will come to Tech Ex. Therefore, a general profile (e.g. therapeutic and cancer) may produce only a few hits per week. For those inventions you

receive that are of no interest, you can quickly reply by email to the university and be done with it. This may be a better strategy than trying to narrowly define your interests. You will NOT have to contend with a daily data dump.

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SELECTING KEYWORDS

When you define a profile or write a search use keywords from the <u>list of keywords</u> provided whenever possible. Universities code technology descriptions with appropriate keywords from this list, which is divided into the following three catagories:

- Industries
- Disease Areas
- Applications

Every technology description falls under at least one Industries keyword, but we do not have an exhaustive list of keywords, so there also may be free keywords included in the technology description. We recommend that you write searches using listed keywords and add free keywords as needed.

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SETTING UP A PROFILE OR SEARCH

We have designed an interactive form to help you set up your profiles and searches easily. You select terms, either from the keyword categories or by entering your own free keywords, in two possible groups:

• AND Group - Terms you always want to appear **simultaneously** in technology descriptions sent to you (e.g. Cancer and Therapeutic, might be required of every returned description in a cancer therapeutic profile).

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• OR Group - Terms you want at least one of which to appear in technology descriptions sent to you (e.g. Breast, Prostate, Colon might be OR terms to go with the above AND terms).

As stated above, it is best to keep your searches as simple as possible.

There are two additional Profile and Search options you should be aware of:

- Boolean Searches. You can also write an unlimited standard Boolean search.
- Searching Text. You can also search the entire text of the descriptions rather than just the keywords section. This only works for free keywords. It may be useful if you are looking for very specific things in your technologies, such as specific chemical compounds.

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Format Options for Delivering Descriptions

You can have hits from registered profiles made available to you by one of the following means (note that hits are compiled and returned once per day):

- Email Hits are emailed directly to you. The "reply to" setting on the email is set to the university contact for the technology, making it easy for you to quickly reply to the notification.
- **HTML** You will receive an email message notifying you that new hits have arrived in you account. Then you can log onto your Technology Exchange account and view the descriptions.

Please contact us if you have any questions.

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FAGE TECHNICAL DETAILS	CONTACT US	SECURITY	LOGIN

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