INTRODUCTION Q AND A (10/24)

The Q&A herein are excerpts from "Technology Commercialization Manual. Strategy, Tactics, and Economics for Business Success." (www.tclearningcenter.com). Notation after the heading reflects the (# of excerpts/total Q&A).

The Q&A are for information only. Seek legal or accounting advice for specific situations.

1. What are pitfalls related to technology transfer?

Many inventors think they can do it all on their own. They must cover all of the potential targets and not give up too soon. It often takes a long time to be successful; so don't expect an overnight success. Several key pitfalls are:

a. unwillingness to share with others who have the ability to help maximize the value of their intellectual property (IP) by licensing and/or commercializing it. (That is not prudent because at the moment they own 100% of nothing whereas if the IP where well managed, it might be worth substantially more);
b. trying too quickly to sell/license the IP without completing the technical and business feasibility; hence value and commercialization plans are absent or inaccurate;
c. marketing and promoting the IP "package" when not well prepared and effectively presented to license candidates;
d. in certain situations inventors fail to engage qualified experts when it is necessary to do so; or
e. having unrealistic compensation expectations, thereby not knowing when to say "yes" or "no" to an offer.

2. What are the pros and cons for securing legal and patent counsel assistance when new discoveries are being transferred or commercialized and when should they be involved?

It is not uncommon for an inventor to approaches Patent Counsel or seeks legal advice early even though asset evaluation is often rather superficial at this point. Individuals often develop dislike or ill feeling when legal bills are presented and technology is not well accepted in the market or slower developing than at first projected. If Legal Counsel could direct or offer access to tools for individual to assess an asset prior to significant legal or patent expense; Counsel would probably achieve a long term relationship that might be more profitable than a short term relationship that goes sour due to inadequate upfront assessment so be sure to ask for such help. Most business recommendations are to involve the legal profession when contract is near conclusion. This approach may not be beneficial. Counsel with background in technology commercialization which covers more than intellectual property might benefit creator due to more efficient use of time and better deal making.

3. What types of questions need to be raised if a technology transfer/commercialization effort wants to provide an incentive program to employees? You would like to: 1) determine if there has been an increase in the incentive practice and 2) obtain details on existing or planned programs.

Examples of information to request are outlined below:

a. Has your organization implemented, or is it considering implementing, an incentive compensation system for its technology transfer employees?
b. Do/will all members of the Technology Transfer organization receive incentive compensation, or just a select group ("professionals," managers, etc.)?

c. On what basis is a) the distribution amount calculated and b) the corresponding allocation made (e.g. pool as % of total program income, % of individual deal, % of base salary if organization/personal goals achieved, other)?
d. Who makes the allocation decision?
e. Does/will your incentive compensation program distribute any shares of equity, actual or "phantom," received as partial consideration for a license transaction to a University based start-up company to your employees?
f. Is the amount of incentive compensation for the Technology Transfer organization or the individual limited/capped?
g. Has a "vesting" period been established which triggers the opportunity to obtain incentive compensation? If so, how much time must the employee be on staff prior to program participation?
h. If the individual leaves the Technology Transfer organization, will the individual be able to receive "earned" incentive compensation after their departure (note: presumes that the incentive compensation is based on individual deals and/or equity participation)? If so, a) is this only possible if the employee is "vested" and b) does this last in perpetuity or is it for a finite period of time after departure?
i. Have you received any negative feedback from the faculty, administration, or other employees due to the incentive compensation system or have there been any other ramifications?
j. Can you quantify a) your ability to attract/retain high caliber professionals since your implementation of the incentive compensation program and b) your organization's growth/increase due to the same?

4. Is technology transfer a competitive venture?

Yes, investors have finite funds and those with similar technologies vie for the same investor in many cases. Government laboratories will become major competitors with universities in transfer of technology. These labs have large $20B research budgets (as high as $20B), 100K scientists and hold many patents (i.e. 28K). Currently few American companies take advantage of federal research. Private and public institutions are advertising in technology transfer news publications and via the Internet. These same firms also preview their technology and research as they attempt to formulate key relationships designed to move discoveries to market.

5. What is the Bayh-Dole Act, what prompted it, and why is it important to university technology transfer?

Enactment of the Bayh-Dole Act (P.L. 96-517), the "Patent and Trademark Act Amendments of 1980" on December 12, 1980 created a uniform patent policy among the many federal agencies that fund research. Bayh-Dole enables small businesses and nonprofit organizations, including universities, to retain title to materials and products they invent under federal funding. Amendments to the Act also created uniform licensing guidelines and expanded the law's purview to include all federally funded contractors. (P.L.98-620)

Critical pressures prompted the Bayh-Dole Act in 1980. Congress perceived the need for reliable technology transfer mechanisms and for a uniform set of federal rules to make the process work. One major impetus for the bill was the lack of a capability on the part of the federal government to transfer technologies for which it had assumed ownership. Hundreds of valuable patents were sitting unused on the shelf because the Government, which sponsored the research that led to the discovery, lacked the resources and links with industry needed for development and marketing of the inventions. Yet the government was unwilling to grant licenses to the private sector. The few federal agencies that could grant patent title to universities were over regulated with conflicting licensing and patenting policies. Technology transfer under those conditions was operationally prohibitive for universities and made them reluctant to enter the technology arena.

Since U.S. industry also was not inclined to brave government bureaucracy to license patents from universities or from the government, limited technology transfer was accomplished by the publishing of research results, training of students for the workforce and some extension programs established by the land-grant universities. The benefit to U.S. industry of such an unstructured process is undocumented and highly speculative.

The stability provided by the Act, its amendments and clear implementing regulations has spurred universities to become involved in transfer of technology from their laboratories to the marketplace. The ability to retain title to and license their inventions has been a healthy incentive for universities. Such incentive is needed, since participation in patent and licensing activities is time consuming for faculty, and must be done in addition to research and teaching priorities. The number of U.S. patents issued to universities has increased sharply since Bayh Dole was passed.

6. How has the Bayh-Dole Act influenced university technology transfer over the last decade and what are the results?

Bayh-Dole gave universities control of their inventions. By placing few restrictions on the universities' licensing activities, Congress left the success or failure of patent licensing up to the institutions themselves. That foresight has been rewarded by skillful and committed university professionals who have shown that licensing embryonic inventions can be successful. The keys are inventors motivated to engage in the process and a licensing relationship built on partnerships with industry. This model is now emulated by the federal laboratories.

The success of Bayh-Dole in expediting the commercialization of federally funded university patents is reflected in the statistics. Prior to 1981, fewer than 250 patents were issued to universities per year. Slightly over a decade later, almost 1,600 were issued each year. Of those, nearly 80% stemmed from federally funded research. In addition, the number of universities participating in the patenting effort has increased to the point that in 1992, 200 universities had at least one patent issued annually.[1]

Core technologies, likely to spark whole new industries, often result from university patents. This potential makes the contributions of the university sector to the national patent pool so significant. Examples range from the biotechnology to the laser industry. Stanford's Cohen-Boyer patent on basic gene splicing tools is at the heart of the entire biotechnology industry. The Axel patents, from Columbia University, provided a new process for inserting genes into mammalian cells to make protein. A host of new pharmaceutical products resulted from this invention.

The Atomic Force Microscope, invented at the University of California, Santa Barbara, is the most advanced atomic microscope in existence. The invention has not only significantly improved our ability to study the structure of molecules important in biology and medicine; it also helps scientists comprehend the subtle details of physiological and chemical processes as they occur in real time.

The field of Magnetic Resonance Imaging, as we know it today, has its roots in research at the University of California, San Francisco. This University-developed technology was first disclosed in the mid 1970s. Later university work in this area and productive partnerships with industry have led to continual advancement in the field. Today, Magnetic Resonance Imaging is a staple in modern medical care.

University gross licensing revenues of approximately $200M in 1991 and $250M in 1992,[2] are a striking indicator of how many university-owned patents have become marketplace products or are in the process of development by industrial companies. Bayh-Dole has enabled laboratory advances to become a significant factor in U.S. industrial growth.

7. How many research universities have technology transfer offices and what do they do?

It is not known exactly how many universities are engaged in technology transfer activities. One indicator is that over 230 U.S. universities and nonprofit research institutions are

represented in the Association of University Technology Managers (AUTM). Among those universities that are active, one can observe a variety of structures and sizes. More significant than the structure of those officers, however, is their mission.

The mission of university technology transfer/licensing offices is to transfer research results to commercial application for public use and benefit. The office seeks and receives reports of inventions from investigators; reports the inventions to sponsors; decides whether to elect title for inventions

[1] *AUTM Survey, compiled annually by Ms. Kathleen Terry, State University of New York at Buffalo*
[2] *AUTM Licensing Survey, 1993.*

developed with external funding; files patent applications; markets those patents to industry, and negotiates and administers license agreements. The technology transfer office is also responsible for oversight of patent prosecution, recording of income and disbursements, and yearly reports to the government.

The major effort of the office is to find companies which have the capability, interest and resources to develop embryonic technologies into useful products. Once a match is found, a license agreement is negotiated to ensure that the company will be diligent in its efforts and will provide a fair financial return to the university - one that reflects a portion of the university's contribution to the return the company receives.

Technology transfer operations are generally also involved in negotiating material transfer agreements. Under such agreements, investigators share research materials (cells, cells lines, reagents, or other organisms) with colleagues in other universities or industry. Technology transfer experts also review the intellectual property terms in sponsored research agreements with industry (in some cases actually negotiating these agreements in conjunction with the university's Contracts and Grants office). Importantly, the professionals in the office are also a resource to the campus on a wide variety of intellectual property matters.

8. How does university technology transfer work and what do universities license?

The major steps in technology transfer are: disclosure of inventions; record keeping and management; evaluation and marketing; patent prosecution; negotiation and drafting of license agreements; and management of active licenses. University technology transfer is mainly a system of disclosure, patenting, licensing and enforcement of patents and licenses.

The disclosure document contains information about the invention, the inventors, the funding sources, anticipated bars to patenting (such as publications), and other data (such as likely candidates for licensing). The licensing staff or a university committee, who make a preliminary decision about ownership and the invention's potential commercial value and patentability, reviews the disclosure. The technology transfer office takes action to insure that the newly disclosed intellectual property will be handled in compliance with federal and university policies.

The next step is to seek an opinion on the patentability of the invention or to file a patent outright. The technology transfer office then markets the invention to industry. A nonconfidential summary is sent to companies that are likely to be interested. If a company expresses interest, it will be asked to sign a secrecy agreement (to protect patent rights) prior to receiving confidential information from the university. If the company continues to be interested after reviewing the confidential information, an agreement with the company is negotiated. This can be a letter of intent; an option; or a license.

In conjunction with any one of these options, a research agreement may be negotiated to continue work on the invention at the university. Most university inventions are embryonic and require further research and development before they are ready for the market place. Thus, there is a high level of risk for the licensee - a fact that is taken into account in the licensing negotiation.

Technology transfer offices have many different "customers" with sometimes conflicting objectives. For instance, customers may consist of the:

a. faculty/inventors, who often have expectations of research opportunities, income, public utilization and fame;
b. private sector, with expectations of securing commercially viable technology at a fair price;
c. university administration, which expects the office to be self-supporting and wants to prevent conflicts of interest;
d. governing board, which needs assurance that the university's name and reputation are protected in its industrial relationships;
e. taxpayers, with expectations that the office will manage state and federal resources in an effective and nondiscriminatory manner; and
f. sponsoring agency which insists on compliance with provisions of the Bayh-Dole Act.

In addition, the technology transfer office has the critical task of insuring that the missions of the university - education, research and service - are not compromised by the business interest emerging from the technology licensing function.

9. How is value realized in the transfer process?

License fees and royalties are determined by arm's length negotiations between licensor and licensee. Fees and royalty rates are rarely large because most of the technology is in early stages and risky, thus requiring considerable investment to transform it into a marketable product. There are, however, a few technologies that have clear commercial applications and have large potential markets. In such cases, the university can negotiate larger fees and higher royalty rates. The deciding factors are: the type of technology, its stage of development, the size of the potential market, the profit margin for the anticipated product, the amount of perceived risk, the strength of the patents, and the projected cost of bringing a product to market.

To place this in perspective, license fees rarely reach into the six figures for a single patent, but more often range from a few thousand to a few tens of thousands of dollars. Royalty rates range from less than one percent (for some process technologies) to perhaps eight percent (for a patented compound with a significant market). The majority of royalty rates are in the 3% to 6% range, based on net sales.

The marketing process itself sets the value of the technology -- how interested are the prospective licensees. Other factors that play a role are the estimated dollar value of the research which led to the discovery; the projected cost of development needed to complete the product; the scope of the license (exclusive vs. nonexclusive; U.S. vs. worldwide; narrow vs. multiple fields of use, etc.) and royalty rates for similar products.

Beyond such general considerations, many organizations seek to accomplish several basic goals in development of the package of considerations: a) the licensee should fund the patent application either through an up-front fee for reimbursement of costs already incurred or through a requirement to reimbursement of ongoing expenses; b) the license agreement should include ongoing considerations to the organization (a royalty); c) required minimum annual royalties after a specified period of time regardless of actual sales; and d) performance milestones to assure that the technology enters the market. This "formula" hopefully assures that the technology is developed to completion and put in the stream of commerce, assures a fair return to the organization, and assures that the technology is returned to the university should the licensee not pay the minimums or achieve the specified performance milestones.

10. What factors influence university decisions to license patents either exclusively or non-exclusively?

University decisions on whether to license a patent only to one company or to a number of companies are based on several factors. However, universities are generally most influenced by two major determinants: (1) what kind of licensing is most likely to lead to rapid commercialization; and (2) what kind of licensing is in the public interest.

Patents which are broad in scope and can be used in multiple industries, or patents that are so basic that they form the building blocks for new technologies are most likely to be licensed non-exclusively, or by fields of use. An exclusive, "field-of-use" license is a way to protect a market for a company while enabling the university to identify more than one licensee to assure public utilization of the technology in all markets.

Stanford University's Cohen-Boyer patent is an example of a basic patent that was licensed to all companies needing it. Non-exclusive licensing is preferred by universities when the technology can be used to foster product development in many fields of use. For example, if a technology will be of greatest benefit to the public if it becomes an industry standard, the university will make it readily accessible to all interested parties.

Universities most frequently will grant exclusive licenses to patents that require significant private investment to reach the marketplace or are so embryonic that exclusivity is necessary to induce the investment needed to determine utility. Frequently, these are new drugs requiring time-intensive and capital-intensive development or they are technologies that have only a tenuous link between the workbench and production. As such, they require a company willing to dedicate financial backing and the creativity of its own scientists on a long-range basis.

At the final call, the decision to license on an exclusive or non-exclusive basis is inevitably driven by market interest. Not only does the interest relate to the value of the invention, but also to the investment required to develop new products and the risk associated with that technology.