

Opportunities and Perils for Technology Transfer through Licensing and New Business Formation: A University Perspective

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Introduction: This paper reviews the opportunities and perils for technology transfer through licensing and new business formation from the perspective of U.S. universities. It is applicable, however, to any public research organization that is protecting the intellectual property rights related to research results of its employees for potential commercialization. This can include government research laboratories and non-profit research institutes. Opportunities and perils are viewed both for the university and its constituents and for the larger society in which it exists and to which it contributes.

In my article titled “University Technology Transfer in the U.S.: History, Status, and Trends” [19] which was made available at the web site for this conference, I point out that technology transfer through licensing and new business formation is a relatively new activity in the United States. When the Stanford University Office of Technology Licensing was launched as an experiment in 1969, there were very few such activities in the United States. Per the most recent (2002) survey of the Association of University Technology Managers (AUTM) [2], the five offices with a starting date prior to 1969 were: Wisconsin Alumni Research Foundation (WARF - 1925), Iowa State University Foundation (1935), Massachusetts Institute of Technology (MIT - 1940), Kansas State University Research Foundation (1942), and University of Minnesota Foundation (1957).

And four of the five were foundations and thus a separate organization from their host institution -- to locate this “commercialization function” away from the core teaching and research missions of the university. The vast majority of the now over 200 such offices in the U.S. (with very few as separate foundations), were formed after the passage of Public Law 96-517 (frequently referred to as the Bayh/Dole Act) in December 1980. Thus, the acceptance of this activity at most U.S. universities, as reflected in forming a dedicated office for it, is only within the last 25 years. And yet, for most of the rest of the world, the U.S. is seen as far ahead in the promotion and support of university technology transfer through licensing.

Summary of Opportunities:

The opportunity for the efficient conversion of innovation into goods and services to stimulate economic development and growth, create jobs, and improve the standard of living.

The opportunity to demonstrate that investment of public funds into research support at universities produces tangible benefits for society.

The opportunity for the university to acquire income from license royalties or the sale of equity from licenses to start-up companies, to support teaching and research activities.

The opportunity for employees of universities (such as university professors) to supplement income through a share of royalty income from the licensing of their inventions, paid consulting work for licensees, or compensation for serving on Advisory Boards of licensees.

The opportunity for licensees to fund research projects in the laboratory of the inventor, when such research funding meets the criteria of the university.

The opportunity for licensees to provide gifts and donations (with related tax benefits) to the university.

The opportunity for licensees to hire students (normally but not always student inventors of the licensed invention) when they graduate.

Summary of Perils:

The peril that patenting and licensing by universities will inhibit rather than promote the progress of science and production of innovation.

The peril of a loss of public trust in the university and/or its employees.

The peril of unfulfilled commitments to research sponsors, to students, or to the university.

The peril of bias when reporting research results, or not reporting research findings that would be adverse to the interests of an industry patron.

The peril of exploiting the work of students to benefit personal interests of their supervising professor.

The peril of adverse and embarrassing reports in the media that adversely affect the reputation of the university.

The peril that new discoveries made by university employees are not reported to the university as invention disclosures, but are instead diverted to a company in which the employee has a financial interest.

Opportunities: Economic Growth and Job Creation

Most attention on the impact of university licensing on economic growth and job creation has centered on Licensed Products sold. And indeed, that impact has been significant. The Annual AUTM Survey, beginning in 1991, has documented the growth in a number of areas for U.S. and Canadian universities and teaching hospitals. Some results from the most recent survey year (2002) [2] are the following:

- Total royalty income of \$1,267 Million, which translates into about \$60 Billion in licensed product sales and over 400,000 jobs
- 15,573 invention disclosures
- 7,741 patent filings
- 4,673 new licenses, with some 10% to start-up companies

Year	Patents Filed	Licenses Granted (Millions of USD)	Royalty Income
1991	1643	1278	186
1992	1951	1741	248
1993	2433	2227	323
1994	2429	2484	360
1995	2872	2616	424
1996	3261	2741	514
1997	4267	3328	611
1998	4808	3668	725
1999	5545	3914	862
2000	6375	4362	1260
2001	6812	4058	1071
2002	7741	4673	1267

Note: The FY2000 Survey included three one-time events totaling \$293 million: a \$200 million settlement of a patent dispute between University of California and Genentech; a \$67 million gain from the sale of Medarex stock by Dartmouth College; and a \$26 million gain from the sale of stock by Georgetown University. Adjusting for these events, the amount is \$967 million.

Some other statistics from the AUTM 2002 Annual Report:

- Five hundred and sixty-nine (569) new commercial products based on university discoveries were reported as launched in 2002.
- Four hundred and fifty (450) new start-up companies were established in 2002, for a total of 4,320 since 1980, with 2,741 still in operation.

There were a number of other surveys done prior to 1991. Ashley Stevens has collected many of these and compiled the information in an article published in *les Nouvelles* in 2003 [23]. He reports that over the time period 1979 through 2002, royalty income has grown at an average compound growth rate of 26.8% per year.

Another source of economic growth and job creation is the pre-production investment by companies in bringing licensed products to market. A study was published in 1995 [16] based on MIT data, and reaffirmed in 1997 [12] based on University of Pennsylvania data, that on average about \$1 million is invested in pre-production each year per exclusive license granted. In 1995, it is estimated that for all U.S. universities, exclusive licenses produced \$4.6 billion in pre-production investment and 27,000 new jobs.

A comprehensive survey, based on the AUTM survey, was initiated in the United Kingdom (UK) in 2001. The results for the financial year 2002 were recently published [15]. Of the 125 universities participating in the survey, about two-thirds started their technology transfer office after 1994. Although licensing to existing companies is done

by most of the offices, the emphasis in the UK is more on start-up company formation compared to the US. While the percentage of new license agreements granted to start-up companies in the US is near 10%, in the UK it is over 17%. And while total 2002 royalty income is modest by US standards (22.4 million pounds), many licensing programs are of recent origin and thus have not had the time to see licensed products reach the marketplace. What is impressive is the growth rates over 2001:

Invention disclosures increased 19%

Number of people involved in commercialization activities increased 24%

Licensing income increased 21%

Number of patents issued increased 59%

Licenses granted increased 39%

Thus, the impressive growth rates shown in the AUTM surveys appear to be repeating in the UK, which suggests university licensing and new business formation will make a significant contribution to economic growth and job creation in the UK in the future.

Opportunities for Universities and its Employees:

The experience of Stanford University reinforces the theory that the most important parameter defining significant royalty income is the length of time the licensing office has been in existence. Certainly other factors play a role [18] but it is instructive to note that the total cumulative royalty income for Stanford for the years 1969 – 1980 was \$4 million, for the years 1981-1990 was \$40 million, and for the years 1991 – 2003 was \$550 million. However the majority of the \$550 million since 1991 can be traced to inventions disclosed to the licensing office in the 1970s! Thus, it takes a combination of invention disclosures with commercial potential and time (sometimes 10 to 15 years or more after initial invention disclosure) before high-volume licensed products sales produce large royalty incomes. And it is typically a very small number of licensed inventions that create most of the income. For Stanford, in fiscal year 2003 [22], 442 licenses generated \$45.4 million, but only seven generated over \$1 million, and those seven accounted for 71% of the total income. All but one of the seven inventions were disclosed to the licensing office before 1985.

Success Story: Stanford was fortunate that one of the largest royalty producing inventions in its history was disclosed in 1971, shortly after the Office of Technology Licensing (“OTL”) was formed. However, this invention, a computer-based sound synthesis technique that could replicate musical tones, required computer equipment that filled a very large room. It was shown to companies producing musical instruments in the U.S., but none could see any value or use for the invention. In 1974, Yamaha (a major manufacturer of musical instruments in Japan,) was asked to review the invention and OTL was invited to the Los Angeles, California sales office of Yamaha to demonstrate it. Fortunately, an engineer based at his company's headquarters in Japan, who was in the U.S. to investigate the emerging new technique of digital sound generation, was visiting his company's office in Los Angeles. By chance, he happened to sit in on a presentation of the invention given by the inventor, a Professor in the Music Department at Stanford. Although this invention had been shown to many others, only this engineer recognized the potential. He became an invention advocate, and convinced

his company to become licensed, predicting that a commercial product using this invention could be produced within 10 years. And 10 years later, in 1984, the first licensed products were introduced by Yamaha (keyboard-based sound synthesizers). Later, packaged in chip-sets, the technology was used as sound generators in personal computers. These products were highly profitable for the company, and Stanford received over \$23 million in royalties. In 1989, Stanford developed a follow-on technology and an alliance was created between Stanford and Yamaha. That young engineer who saw the invention potential for his company subsequently became President of Yamaha.

It is now an accepted practice for universities to receive shares of stock (i.e., equity) as partial compensation for granting a limited-term exclusive license to a start-up company. At Stanford, the number of shares is typically in the range of 2 to 5% of the founding equity, with a provision that this percentage will remain unchanged through the first investor round (usually called the Series A round) by the granting of additional shares at no cost to Stanford. Most licensees will also permit the university to acquire additional shares in later financing rounds, by payment of the issuing price for the shares, to maintain its ownership percentage. Stanford policy is to sell such shares as soon as there is a public market. To date, Stanford has received \$23 million from the sale of equity, with two companies accounting for most of the amount. However Stanford does hold a large block of equity in Google, and this may result in a substantial one-time source of income when Google holds its Initial Public Offering (IPO).

Success Story: The largest return to Stanford from the sale of equity to date (just under \$10 million) was from the start-up company Abrizio. The story begins in 1998 when I received a telephone call from a Professor in our Electrical Engineering Department. He had been contacted by a person then working in Seattle, Washington, who had learned about a very high-speed digital switching technique this Professor had developed. He had come to Stanford to meet with the Professor, and proposed they form a new company to commercialize the technology. The Professor agreed, and arranged a one-year leave of absence from Stanford to be the Chief Technical Officer for the newly formed company. In talking with potential early investors in the start-up company, they asked if the company had a license to the technology from Stanford, and thus his call to me.

Upon investigation, I learned there had not yet been an invention disclosure for this technology, and the key features of it had been publicly disclosed over one year ago. Thus, a patent for it was not possible. Further, the research work of the Professor had been sponsored by two large companies in the telecommunications industry, the primary market for the technology. These companies thus had a non-exclusive right to any intellectual property related to the technology, greatly diluting the value of an exclusive license to the start-up (Stanford's definition of exclusive is that it will not grant any further licenses to the licensed invention).

The only licensable aspects of the technology turned out to be computer-based design files. I asserted Stanford probably had an ownership right to the copyright to these files, and this was the basis for the license to Abrizio, the chosen name of the start-up

company. Because we had very little in the way of protected intellectual property (as the negotiators for Abrizio frequently pointed out during our license negotiations), I suggested this would be a paid-up license in exchange for 50,000 shares of Abrizio stock, which they accepted. This was the first and only license I have negotiated where only shares of stock are the total compensation for a license.

It was about two years later that I received another telephone call from the Professor. He had returned to Stanford following his one-year leave of absence, and he wanted me to know Abrizio was about to be acquired by a large telecommunications company, for \$400 million. There had been more than one splitting of the stock, so the number of shares owned by Stanford had grown (note: per Stanford policy, 1/3 of the initial 50,000 shares had been distributed in equal amounts directly to the Professor and four of his graduate students, who were the named inventors of the licensed technology on the invention disclosure I requested and received following the first telephone call). By the time Stanford's shares in Abrizio had been converted to shares of the acquiring company (PMC Sierra) and could be sold, the share pricing had shot up to over \$200 per share (this was during the internet/telecom bubble) and Stanford received \$9.7 million for the shares it owned.

Many inventions created at universities are at a very early stage of development. Further research and development will be required before they can become commercial products. In some circumstances, the research part may coincide with the research interests of the inventor, and the licensee may choose to negotiate a sponsored research agreement for such research work. At Stanford, many millions of dollars of research support are performed every year that are linked to a license agreement. Licensees also frequently wish the inventor to serve as a paid consultant, to provide know-how and show-how as licensed products are developed. And the inventor may be asked to serve on a licensee's Advisory Board, such as a Scientific Advisory Board, for which compensation is provided.

Under the provisions of the Bayh/Dole Law, a percentage of royalty income must be shared with the inventor(s). Each university can set its own royalty sharing arrangements. At Stanford, after 15% is set aside for the operations of the licensing office and for certain programs, the balance is shared 1/3 with inventor(s), 1/3 with the inventor(s) department, and 1/3 with the inventor(s) school. There is no cap on the total amount shared with Stanford inventor(s), and a few have received millions of dollars from the licensing of their inventions. Some universities have the percentage given to inventor(s) change as the total amount reaches certain levels, or may set a threshold amount after which no further payments are made to the inventor(s).

Licensees may also provide donations as part of their relationship with the university. In the U.S., such donations to a qualifying institution (such as a university) are tax deductible with such tax deductions contributing to licensee profits. Such donations can be in the form of cash, which may be directed to research areas of interest to the licensee, or equipment. One company in the medical imaging area was provided donations of their expensive medical imaging equipment to Stanford, recognizing that the researchers

utilizing such equipment in their research will reference such equipment in published articles, and they may also discover ways to improve the equipment. For example, one such discovery reduced significantly the power requirements for imaging, which provided this company a significant competitive advantage when this was incorporated into its equipment.

The license relationship can also build a bridge between the licensee and the laboratory of the inventor(s). This sometimes allows the licensee early access to new discoveries within the lab and to assess the capabilities of the graduate students conducting research. Often such students are co-inventors of the licensed invention. The licensee may offer the students employment upon their graduation, providing skilled labor knowledgeable about the licensed technology.

Universities vs. For-Profit Industry:

Clearly there are significant differences in the mission and operation of a university and for-profit industries. The primary role of a university is education of students and creation and dissemination of new knowledge. The primary role of industry is to increase shareholder value through successful competition in the local, national or global marketplace. Academic research should be curiosity-driven basic research extending the boundaries of knowledge. The faculty set research directions and priorities, and freedom to publish and discuss research results freely with others is fundamental. Work in industry laboratories is normally guided, monitored, and directed by company management, with results held confidential and with the objective of creating products and profits for the company. It is therefore not surprising when these two very different cultures seek to collaborate, compromises are needed.

Industry has found that building allegiance and dedication of key people can be facilitated by financial participation in successful outcomes. Thus, profit-sharing or issuance of stock options is used to create allegiance and motivate people towards high performance. Universities cannot provide such financial participation, but industry (and especially newly formed companies) can offer such inducements to university faculty, creating potential problems of conflict of interest and conflict of commitment to university responsibilities.

University Presidents and Senior Administration are entrusted with maintaining and enhancing the reputation and goodwill in the university's name and trademarks. This is critical in recruiting the faculty and graduate students necessary in building and maintaining a strong university. Thus, any potential situation which threatens the institutions integrity and reputation is treated very seriously. And thus policies and operating guidelines that provide education of faculty as to what is permissible and what is not, coupled with early warning systems that ensure early detection of potentially serious conflict situations, are carefully considered and crafted.

The dictionary defines conflict of interest as: "A conflict between the private interests and the official responsibilities of a person in a position of trust". Our Federal

Government provides a somewhat different definition as follows: "A conflict of interest exists when the designated official(s) reasonably determine that a significant financial interest could directly and significantly affect the design, conduct, or reporting of government-funded research".

Conflict of interest is associated with financial issues. Conflict of commitment is associated with time management issues. In this document we will refer to them collectively as COIC.

Conflict of Interest and Commitment: Societal Impact

Innovation is the lifeblood of economic progress. The rapid and efficient dissemination of new knowledge from public research organizations (such as universities) creates the knowledge commons upon which further new knowledge is built. Actions that inhibit or restrict such flow of knowledge would be of serious societal concern. Likewise, the sharing of research materials and "tool-sets" that permit more rapid advancement of knowledge is important to the efficient production of new knowledge. Actions that inhibit or restrict the free sharing of such materials or tools would be of serious concern. As university researchers build ties to industry that provide the opportunity for financial gain from product success, the opportunity to influence the availability or the content of research results related to such products becomes a concern. There is also the opportunity to withhold research materials and/or research tools that might aid development of a competitive product.

There are also some who believe a focus on commercial gain from university discovery, especially in the biomedical area, is causing the patenting (and potential exclusive licensing) of very early-stage inventions. As asserted by Rai and Eisenberg [17] "The tradition of open science has eroded considerably over the past quarter century as proprietary claims have reached further upstream from end products to cover fundamental discoveries that provide the knowledge base for future product development." They suggest universities are filing for patents on discoveries that should instead be placed in the knowledge commons, and that the NIH should review invention disclosures linked to NIH funding to identify those where patent applications are not appropriate.

Donald Kennedy, former President of Stanford University, [11] shares a similar concern with regard to "the precious storehouse of public germplasm – seedbanks, landraces – developed by nations and by the international research centers." He worries that public firms can patent genetic discoveries based on this knowledge base, and disrupt widespread crop development to feed the developing world.

Derek Bok, former President of Harvard University, in his book *Universities in the Marketplace* [4] expresses his concerns on page 77 as follows: "Universities have paid a price for industry support through excessive secrecy, periodic exposes of financial conflict, and corporate efforts to manipulate or suppress research results" and "In the face of pressure from corporate sponsors to influence the results of high-stakes clinical

research, institutional safeguards have proved inadequate in a disturbing number of cases. Most universities have not done all they should to protect the integrity of their research. Many have not even shown that they are seriously concerned about doing so.”

Bok also references a study done by Deborah A. Barnes and Lisa A. Bero that found 94% of authors of studies done on the effects of passive smoke on human health with ties to the tobacco industry reported no harmful effects. Of those authors doing similar studies, but without ties to the tobacco industry, only 13% reached the same conclusion.

Sheldon Krinsky, a policy analyst at Tufts University School of Medicine, is highly critical of the growing intimate relationships between university researchers and the pharmaceutical industry [13]. He claims it is common for university attendees at scientific conferences to receive gifts, travel reimbursement, payment of fees, and evening entertainment from corporate sponsors. He also claims about a quarter of scientists working in medical research have some sort of financial relationship with industry.

Conflict of Interest and Commitment: Institutional Concerns

COIC can occur at both the institutional and individual level. Institutional conflicts may occur when developing research agreements with industry, when developing licensing agreements with industry (especially when equity is taken), and in gifting arrangements with industry. The company providing a contribution to the university (normally money but could be other things such as equipment) may seek to influence the design, conduct, or reporting of research in ways that are beneficial to the company, or the researcher may be tempted to alter research activities in a way that might attract contributions from industry. Companies may seek to have delays in publication of research results, or the right to approve the content in publications, or even the right to edit out information so only the company has access to it.

With regard to licensing, the institution may provide first opportunity to license important inventions to selected individuals or companies (referred to as "pipelining") or may give very favorable licensing terms to selected individuals or companies. There is also the issue of use of the institution's name and goodwill for the benefit of the business, or access and use of university facilities for company benefit. These potential conflicts would be even more troubling if any of the Officers of the institution have a financial interest or connection to the company or if the institution holds a significant equity position in the company. And the institution must be especially diligent about conflicts when human subjects are involved in the research program.

There is also the danger that an employee of the university may not disclose new discoveries to the university through the filing of invention disclosures, but instead diverts the invention to a company in which the employee has a financial interest. As most research work is funded by outside entities (e.g., the federal government), there is an institutional obligation to notify the sponsor of the research of such inventions and to honor contractual obligations concerning intellectual property rights. If such situations

arise, it can be difficult and costly if legal action is required to regain such rights. This was the case with Fenn v. Yale University, 2003 WL 22160423 (D Conn. 2003). In this case, Dr. Fenn, a Nobel laureate chemist, did not disclose an invention he made under funding from the NIH when on the faculty of Yale University. He did file for a patent in his own name, financed by a company he had founded. He then exclusively licensed his patent to the company and received royalty payments. When Yale learned of the patent and the license, it demanded Fenn assign the patent to the university. When Fenn refused, and sued Yale for interfering with his company's commercialization of "his" invention, Yale countersued. The Court found in favor of Yale on its breach of contract, breach of fiduciary duty (to file an invention disclosure with the university) and fraud claims.

Another potential source of legal problems are the agreements to protect proprietary information or materials that university researchers enter into when receiving such proprietary items from companies they have a relationship with. Universities are open environments, and university researchers like to show or tell people about their work. If they do not properly protect such proprietary items, it could lead to embarrassment, or worse, legal action against the individual and the university.

Conflict of Interest and Commitment: Individual Concerns

With regard to individual COIC, faculty members have considerable leeway in structuring their research programs and in the allocation of their time. They also have considerable influence over the graduate students they supervise and, in most instances, to whom they provide financial support. And they have control over when and how research results are reported. If suitably motivated, a faculty member can take actions in the design, conduct, or reporting of research that would be highly beneficial to a company, and perhaps not in the best interests of the university or his/her graduate students. Such actions include: (1) directing graduate students to work on solving problems of a company; (2) deviating from basic to more applied research that is of value to a company; (3) provide access to and use of university facilities for the benefit of a company; and (4) editing out or altering data in a way that benefits a company when publishing research results. A faculty member may also become so committed to tasks for a company that there is not sufficient remaining time to fulfill university responsibilities.

Managing Conflicts of Interest and Commitment

Stanford University is one example of a university that has given significant attention to creating policies and guidelines related to conflict of interest and commitment. Separate policies exist for faculty, staff, and students. A listing of the policies can be found at the website www.stanford.edu/dept/DoR/ad_hoc.html.

Underlying Stanford's approach is the recognition that for effective management of potential and actual conflicts, you must have an early warning system that demands full disclosure. Potential conflict situations must be identified at or near the time of

inception, so that review and adjustments (if needed) can be taken before the situation advances to a stage that can bring harm to the individual, the institution, or both. Stanford requires an annual conflict review for all faculty and those staff in positions where conflict might arise. This review requires the identification of all outside activities that could produce conflict situations. The annual review document is provided as Attachment A. In addition, the policies identify ad hoc situations that would require a one-time conflict review tied to that unique situation. An example of an ad hoc situation is when a university employee, such as a Professor, will be involved with a start-up company that is seeking a license from the university. An ad hoc conflict review must be completed and approval given before the license will be granted. The Ad Hoc Disclosure Template is provided as Attachment B. As part of an Ad Hoc conflict review related to the licensing of a start-up company, OTL must also complete a form about the proposed license arrangement. This form is provided as Attachment C.

Situations that involve human subjects in research programs are especially sensitive. The results from human clinical studies can have enormous impact on the profits and stock price for the companies conducting such trials. Thus, universities that conduct such clinical trials must be especially vigilant to ensure no conflict issues can arise. Stanford University has a policy of not holding any shares of stock in companies that have commissioned clinical studies at its Medical School. If Stanford should have any shares of stock, they will be sold before the clinical studies can start.

The policies at the Howard Hughes Medical Institute (HHMI) as reported by Cech and Leonard [6] are more stringent than most U.S. universities. Its scientists cannot hold more than 5% equity interest in a company that is a consulting client or equity received for services to a start-up company. Scientists cannot be a consultant to a company that has a collaboration arrangement with HHMI. And HHMI requires that every agreement with a commercial entity, including consulting agreements, must be reviewed and approved before being signed. It is the review of consulting agreements by the institution that differs from the practices of most U.S. universities.

Harvard Medical School in 2004 revised its policies on conflict to permit Harvard faculty to own up to \$30,000 in stock from public companies that benefit from their research [5]. They cannot have any stock from companies with which they have ongoing research collaborations or in private companies related to their research. They can, however, receive up to \$20,000 in consulting fees from companies tied to their research. Faculty also cannot hold management positions with firms, such as chief scientific officer or chief medical officer.

Conflict Examples

Example 1: This example is from the first of a series of symposia held at Stanford University in 1982 on the topic “Universities, Industries, and Graduate Education” - as reported by Lee Randolph Bean in the October 1982 Hastings Center Report [3]. Stanford’s President, Donald Kennedy, presented this example to illustrate the problems

that arise as faculty members move from the role of teacher/investigator to that of entrepreneur.

Professor X and his graduate students work on a basic molecular biology project. Dr. X also is a consultant and share-holder in Clotech, Inc., which has built a scaled-up facility for producing and testing a useful protein that is the primary gene product from a plasmid Dr.X first got from bacteria cells. Stanford, which has an assignment to the patent on the product, is now considering offers to invest in Clotech, and also plans to offer an exclusive license to Clotech for a related process on which Stanford holds patent rights. Meanwhile, Mr. Y, a graduate student good at purifying the protein, has complained to the university ombudsman that X is using every means at his disposal to induce him to undertake outside employment with Clotech.

The issues Kennedy wished to bring forward for discussion at the symposia were:

Conflict of interest: Is Professor X devoting undue time and effort to Clotech because of his profitable consulting and equity arrangements, to the neglect of his teaching responsibilities? Do his outside ties create competing loyalties between Stanford and Clotech?

Secrecy: Has Professor X kept past research results to himself, because his colleague, Professor Z, works for a competitor company? Did Clotech ask that he delay publication of his work in order to secure an exclusive license from Stanford? [author's comment: should Stanford have marketed the license to the patent(s) to others to determine if another party, perhaps better qualified, would develop licensed products? Or should Stanford seriously consider offering non-exclusive licenses to all interested parties?]

Patents: Should scientific knowledge be owned and traded for profit? Should the university share in that ownership?

Research priorities: Does Professor X's involvement in a commercial production facility indicate a shift in his focus from basic to applied research? Will the future direction of scientific research be skewed to respond to the needs of private industry?

Graduate students: Have Mr. Y's time and talents been exploited for the gain of his advisor's company?

Public perception: Will extensive ties to the private sector erode public confidence in the detachment and trustworthiness of university research?

Scientific norms: The open and free sharing of information, and a disinterested approach to research that puts the advancement of science first are norms that have traditionally governed science, according to sociologist Robert Merton. Are those norms disintegrating as the pull for commercial application of research and consequent profits intensifies?

Example 2: Professor AB in the university's Ophthalmology Department, a renown eye surgeon, disclosed an invention four years ago to the technology licensing office. This invention, an improved technique for precisely cutting soft tissue, holds great promise for eye surgery. A patent, assigned to the university, has issued. It is exclusively licensed to the start-up company EyeCare, Inc., to which Professor AB is both a consultant and the Chair of the Scientific Advisory Board. Professor AB has been given 100,000 shares of

the company stock for his services. The university received 200,000 shares of stock as partial compensation for the exclusive license. In addition, EyeCare has sponsored research in Professor's AB lab for the past three years (ever since the company was formed). When EyeCare first proposed supporting the research of Professor AB, the university established an oversight panel to review research proposals and results, the involvement of graduate students with the company, and to advise Professor AB of potential conflict situations.

Because of this sponsorship, EyeCare has exercised its right to exclusively license three improvement patents resulting from the research. A separate conflict review was required before the exclusive license could be granted. The university licensing office also submitted a report on its marketing the invention to other parties, and a statement that EyeCare is the best alternative for commercialization of the invention in a timely manner. This conflict review very carefully evaluated how the relationship with EyeCare might impact the graduate students conducting research in Professor AB's lab, as the potential for altering the work of students to benefit the company was a major concern.

Example 3: The invention licensed to EyeCare has now reached the stage where clinical studies, with human subjects, will be required to obtain the government approval to sell the medical device in the U.S. The lab of Professor AB is clearly the best source for coordinating such trails, with Professor AB and his colleagues performing the procedures. However the relationship of Professor AB with EyeCare, where he could profit handsomely if the clinical trails are successful, is a cause of great concern. The university must therefore carefully review the situation in order to determine if it will conduct the trails or not, and if it will permit conducting the trials, with what level of oversight and controls.

The university, following a review, decides to conduct the trials with the following oversight conditions:

1. Professor AB must sell all his shares in EyeCare and agree not to acquire any shares in the future, including options to acquire shares.
2. The university will sell all its shares in EyeCare and agree not to acquire any shares in the future, including options to acquire shares.
3. Professor AB will participate in the clinical trails, but will not be the Principal Investigator for the trails.
4. An oversight committee will be formed that will review the results from the trails and any publications related to the trails. The committee will include Professor CD, a respected eye surgeon from another university medical center.
5. Professor AB will fully disclose his relationship with EyeCare in any publications or presentations related to any research connected to EyeCare.
6. Professor AB's relationship to EyeCare must be fully disclosed and explained on the "Informed Consent" agreement signed by every human subject participating in the trials.

Example 4: Referring to Example 1, Clotech has expanded and upgraded the scale-up facility to the point that it will now permit Mr. Y to run experiments in pursuit of his PhD qualifying research work that he cannot do with the facilities in Professor X's lab. Mr. Y's research is fully funded under a U.S. government grant. Clotech is willing to make their facilities available for the research project of Mr. Y, as they realize such work will be very relevant to their product plans. They have requested a right to help guide the research work of Mr. Y, and also requested a document signed by the university stating that any intellectual property created by Mr. Y resulting from the use of their facilities will be owned by Clotech. Professor X is encouraging Mr. Y to utilize Clotech's facilities in his research, and is urging the university to accept the requests of Clotech. Clotech has also indicated that they would be willing to hire Mr. Y as a paid consultant as long as he follows the guidance of Clotech in his research, and that any intellectual property created from the research would be owned by Clotech. Professor X is supportive of Mr. Y being a paid consultant for Clotech under these terms.

Ms. EF in the Office of the Dean of Research has been asked to review the situation and inform Professor X and Clotech what the university's policies will allow in this case. After a careful review, including discussions with Professor X and Mr. Y, her response is as follows:

1. Any intellectual property created by Mr. Y that is related to his research program for his PhD degree, as specified under the work statement in the government grant funding Mr. Y, will be owned by the university. This is regardless of where and with what facilities Mr. Y conducts such research.
2. Mr. Y cannot be a paid consultant for research work that is also funded by the government.
3. A designated Professor in the department of Professor X will become a co-advisor for Mr. Y and will be charged with ensuring the research work of Mr. Y is in full compliance with progress towards his PhD degree.
4. A Collaboration Agreement will be negotiated between the university and Clotech that will spell out clearly the terms of the proposed collaboration, including university ownership of intellectual property created by Mr. Y and the right of Mr. Y to freely publish at any time the results of his research.
5. A meeting will be held with Professor X and the Dean of Research to discuss the situation and to ensure Professor X understands that the university would not allow, under any circumstances, an outside company to direct the research of a graduate student and that ownership of any intellectual property created by a graduate student as part of his funded research work will be owned by the university.

Developing Policies for Conflict of Interest and Conflict of Commitment and for Technology Transfer through Licensing and New Business Formation

For Conflict Policies: The policies created at Stanford University over the past several years governing conflict situations can be found at the web site

www.stanford.edu/dept/DoR/ad_hoc.html. There are separate policies for faculty members, staff members, and students.

Other good sources of information when constructing your own policies are given in the references below, with the most comprehensive being references [1], [7], and [14].

For Technology Transfer Policies: The Association of University Technology Managers (AUTM) publishes a multi-volume Technology Transfer Practice Manual that provides articles on all phases of technology transfer as well as sample policies and transfer agreements. Ordering information can be found at the AUTM web site: www.autm.org. Other comprehensive sources of information are included in the references below, specifically [8], [18], and [21].

References:

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[6] Cech, Thomas R. and Joan S Leonard. 9 February 2001. "Conflicts of Interest – Moving Beyond Disclosure". *Science*. Volume 291. 989

[7] Council on Government Relations (COGR). 2004. "Approaches to Developing an Institutional Conflict of Interest Policy". www.cogr.edu

[8] Council on Government Relations (COGR). September 2000. "A Tutorial on Technology Transfer in U.S. Colleges and Universities". www.cogr.edu

[9] Fondacaro, Joseph D. and Richard J. Kordal. June 2002. "Successful University Licensing: Blending the Academic and Entrepreneurial Cultures". *les Nouvelles*. 45-47

[10] George, Ann. July, 2004. Personal interview with Stanford University Assistant Dean, Research and Graduate Policy

- [11] Kennedy, Donald, Editor-in-Chief, *Science*. “A Second Postwar Revolution for Biomedicine: Enclosing the Knowledge Commons”. Invited Shannon Lecture
- [12] Kramer, Peter B., Sandy I. Scheibe, Donyale Y. Reavis, and Louis P. Berneman. 1997. “Induced Investments and Jobs Produced by Exclusive Patent Licenses – a Confirmatory Study”. *Journal of the Association of University Technology Managers*. Volume IX. 79-100
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- [14] Organization for Economic Co-operation and Development (OECD). June 2003. “Recommendation of the Council on Guidelines for Managing Conflict of Interest in the Public Service”.
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- [17] Rai, Arti K. and Rebecca S. Eisenberg. 2003. “Bayh-Dole Reform and the Progress of Biomedicine”. *American Scientist* 91. 52-59
- [18] Sandelin, Jon. September 1993. “Successful Licensing of Research Results,” *les Nouvelles* - Journal of the Licensing Executives Society, Vol. XXVIII No. 3. 127-129.
- [19] Sandelin, Jon. 2003. “University Technology Transfer in the U.S.: History, Status, and Trends”. Unpublished manuscript
- [21] Sandelin, Jon. 2004. “An Operations Manual for a Technology Transfer Organization”. Technology Innovation Group; www.techingroup.com
- [22] Stanford University Office of Technology Licensing: Annual Report 2002 - 2003
- [23] Stevens ,Ashley J. September 2003. “20 Years of Academic Licensing: Royalty Income and Economic Impact”. *les Nouvelles* Vol 38, 133-140

Attachment A

Annual Certification of Compliance to the Faculty Policy on Conflict of Commitment and Interest

Attachment A to Research Policy Handbook 4.1,
[Faculty Policy on Conflict of Commitment and Interest](#)

Other Available Views: [Adobe Acrobat \(PDF\)](#), [downloadable Word file](#)
[The Word file can be filled out electronically and saved, then printed and signed.]
Located Inside: [Research Policy Handbook](#)

(Note: Individual schools of the University may design their own forms, including more information but not less than that requested below. This disclosure is filed by means of an [online application in the School of Medicine.](#))

Name: _____

Title: _____

Department(s): _____

The following questions apply to activities throughout the preceding academic year:

1. What percent time were you on active duty?

Autumn _____ Winter _____ Spring _____ Summer _____

2. Please list the number of days you engaged in outside consulting activities during the preceding year.

Autumn _____ Winter _____ Spring _____ Summer _____

3. Did you have a managerial or principal investigator role in an activity outside the University? If yes, please list and explain in an attached statement.

No _____ Yes _____

4. Did you (or members of your immediate family, i.e., spouse or dependent children as determined by the Internal Revenue Service, or domestic partner) have an employment, consulting or other financial relationship, including ownership (at least 1/2% of equity or at least \$100,000 worth of ownership interests), with a sponsor of your University teaching or research activities? Please include only that equity which is directly under

your control, not that managed by a third party such as a mutual fund. If yes, please list each such arrangement and provide an attached written explanation.

No _____ Yes _____

5. Did you (or members of your immediate family, as described above) have an employment, consulting, financial or significant relationship, including ownership (at least 1/2% of equity or at least \$100,000 worth of ownership interests), in a company that does business with the University that involves you as an employee of the University? Please include only that equity which is directly under your control, not that managed by a third party such as a mutual fund. If yes, please list and explain in an attached statement.

No _____ Yes _____

6. Did you (or members of your immediate family, as described above) have an employment, consulting, financial or other significant relationship, including ownership (at least 1/2% of equity or at least \$100,000 worth of ownership interests), with an outside organization contributing gift funds to Stanford which are under your control or of direct benefit to your teaching or research activities? Please include only that equity which is directly under your control, not that managed by a third party such as a mutual fund. If yes, please list each such arrangement and provide an attached written explanation.

No _____ Yes _____

7 a. Did you submit a proposal to or receive an award from the Public Health Service or the National Science Foundation?

No _____ Yes _____

_____ IF NO, GO TO QUESTION 8.

7 b. If yes, did you submit a proposal to or receive funding from or conduct research which could benefit a company in which you either had a consulting arrangement or had significant financial holdings (defined by those agencies to be at least 5% of equity or at least \$10,000 worth of ownership interests)?

No _____ Yes _____

_____ IF NO, GO TO QUESTION 8.

7 c. If yes, were those arrangements or financial interests disclosed at the time of proposal submission?

Yes _____ No _____

8. Were you an inventor of intellectual property which has been or will be licensed through Stanford to any outside entity in which you (or members of your immediate family, as described above) have an employment, consulting or financial or other significant relationship, including ownership (at least 1/2% of equity or at least \$100,000 worth of ownership interests)? If yes, please list and explain in an attached statement.

No _____ Yes _____

9. Did you create, discover, or reduce to practice an invention(s) using University resources to which title has not been assigned to the University? If yes, please list and explain in an attached statement.

No _____ Yes _____

10 a. Did you involve any of your students or staff in your outside consulting or pro bono activities? If yes, please list and explain in an attached statement.

No _____ Yes _____

10 b. If yes, was this arrangement prospectively approved by the department chair?

Yes _____ No _____

11. Please describe on an attached sheet, if necessary, any other relationships, commitments, or activities you or any members of your immediate family have that might present or appear to present a conflict of interest or commitment with your Stanford University appointment. Such relationships might include financial or fiduciary interest or uncompensated activities.

CERTIFICATION

In submitting this form, I certify that the above information is true to the best of my knowledge, that I have read the [Faculty Policy on Conflict of Commitment and Interest](#), and that I am in compliance with Stanford policies related to conflicts of commitment and interest. I supply this information for confidential review by the University and I do not authorize release of any of it for any other use.

Signature: _____

Date: _____

Attachment B

Ad Hoc Disclosure Template

Q 1. Name of company with which there is a proposed relationship:

Q 2. Nature of the relationship either EXISTING or PROPOSED. Please check ALL that apply, i.e., if you are currently a founder and a consultant proposing to receive gift funds, you would check both of the appropriate boxes under EXISTING and the gift box under PROPOSED, and enter the amount (in \$ or % equity) of financial interest of each.

Relationship/ activities	EXISTING	PROPOSED	Amount (\$ or %) of financial interest
Founder			
Employee/ Executive Position			
Scientific Advisory Board			
Consultant			
Stock or Ownership Interest			
Gift			
Sponsored Project			
Licensors of Technology			
Clinical Trial			
Other			

Q 3. If you checked either EXISTING or PROPOSED for Sponsored Research, Gift, or Clinical Trial, please answer the appropriate Q1 questions below:

- a. Is the sponsored research being conducted for regulatory approval or does it use a technology licensed to the sponsor? Please explain.
- b. How do you intend to use the gift funds? Please explain.
- c. Is the Clinical Trial testing your own invention or the company's own products? Please explain.

Q 4. What is your role in the proposed activity or relationship (e.g., PI of study, co-investigator, organizer of CME, etc.)? Please explain.

Q 5. Who else will be involved in the activity (students, postdoctoral fellows, etc.) and how?

Q 6. How might the proposed relationship affect your Stanford research, including the research projects of your students and postdocs?

Q 7.

Education and training of students is one of the University's highest priorities. Therefore, the research and scholarship of students and other trainees should be protected from any consequences of faculty relationships with outside entities.

Please explain how you intend to separate any potential conflicts between your University responsibilities (including your research at Stanford, students, postdocs, etc.) and your proposed activities with the commercial entity.

Attachment C

Date:

To: Associate Dean of School

cc: Director, OTL
Associate Dean of Research
Inventor

From: Licensing Associate

Re: OTL Disclosure Docket Sxx-xxx, "Title" Inventors:

Faculty Inventor:

Rank:

Sponsor:

Description of Technology:

Involvement of inventor with proposed licensee:

Proposed Licensee:

Address:

Description of Company: (company life cycle, products, sales, etc.)

OTL Assessment:

1. Why proposed licensee was chosen
2. OTL's marketing efforts and their results
3. General terms of the license (exclusive, non-exclusive)