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INTELLECTUAL PROPERTY ACTIVITIES IN U.S. RESEARCH UNIVERSITIES

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I. INTRODUCTION

The Bayh-Dole Act of 1980 [n1] allows U.S. universities to own and manage inventions obtained using federal funds. This Act laid the foundation for university technology transfer activities in most major research universities of the country. Consequently, the interaction between universities and industry increased significantly as well as the sophistication in university intellectual property management.

The model used for managing intellectual property at the University of Illinois at Chicago (UIC) is efficient and successful, and is the one increasingly used by university technology transfer offices. The model is proactive and deals with all aspects of UIC's intellectual property: disclosure, protection, marketing, negotiating and licensing, as well as intellectual property provisions in UIC's research agreements, material transfer agreements, option agreements, and licensing agreements.

A. Historical Introduction

Scientific investigation in American universities started to become an important part of academic endeavor at the end of the *514 nineteenth century when the very mission of universities began to change from emphasizing cultural values to creating knowledge through the exercise of reason. [n2] Around 1910, about 15 U.S. institutions could be characterized as research universities. Over the next two decades, research activities in these universities were strengthened and expanded, but by the late 1930s, still only about 16 institutions could be classified as research universities.

The expansion of scientific investigation at major research universities occurred in all fields during the past 50 years. The definitive impetus was given after World War II by Vannevar Bush through a document titled "Science, the Endless Frontier," in which he recommended that the U.S. Government fund the conduct of basic research. This recommendation was encouraged, at least in part, by the success of scientific-military projects carried out with significant academic participation, such as the Manhattan Project and the development of radar technology. The goal was to support basic research in academia and in national laboratories with the expectation that researchers would

publish their results in scientific journals, and that this free information would be used by industry to develop new products and processes that would benefit society.

It took about 15 years to implement Bush's recommendations; substantial funding started in the early 1960s and since then has continuously increased. A consequence of this support has been the rapid increase in the number of research universities. This financing continues and in the 1993 fiscal year, it exceeded $18 billion. However, the budgets in terms of constant dollars in the 1970s and so far the 1990s have seen little growth. Industrial sponsorship of university research throughout the 1960s and 1970s contributed only 2-4% of the total funding. However, it has been increasing throughout the 1980s and 1990s and presently stands at approximately 7% of the total funding. In fiscal 1995, UIC had $119 million in its research budget, of which $6.1 million came from industry, which constituted 5.1% of the total funding.

It is estimated that at major research universities, there is approximately one invention disclosure for every $2,000,000 of research funding. In the 1960s and 1970s, following Bush's paradigm, most of the inventions were freely published in scientific journals, with little transfer of technology to industry. The model proved to be inefficient for academia-to- industry or government-to-industry technology transfer. Without the exclusivity that patents provide and the ability to economically exploit that exclusivity, companies would rarely invest large amounts of capital for the development of early-stage inventions into *515 final products or processes. After all, the companies were in business to make money, and therefore, they wanted only to spend money on endeavors from which they were likely to recuperate their investment and make a profit.

Some researchers and administrators foresaw the utility of patents. However, government bureaucracy made it difficult for third parties to obtain exclusive rights to patents on the technology. Before 1980, the government sponsor owned and managed these inventions and only offered non-exclusive licenses. Even these licenses were difficult to obtain due to the cumbersome bureaucratic procedures involved. Thus, only a small number of research universities were engaged in technology transfer until the early 1980s.

But since then there has been an explosion of interest and a flurry of activity in intellectual property and technology transfer on university campuses. This occurred mainly as a result of the passage of the Bayh-Dole Act of 1980. Among other provisions, this legislation allows universities to own and manage inventions obtained in the course of research funded by government sponsors. This change became an incentive for universities to patent their inventions and to attract the attention of industry to make end products from these inventions. Presently, over 250 universities have technology transfer activities and, in 1994, they collectively generated almost $266 million in royalties.

U.S. universities today manage the full spectrum of intellectual property matters. These include the evaluation of inventions disclosed by the faculty; protection of these inventions through patents, copyrights, and trademarks; negotiation of license agreements with industry; creation of start-up companies; ownership of equity in companies which

use the inventive technologies; defense of the patents, copyrights, and trademarks against infringers; and sponsorship of further research with royalty income.

From the perspective of U.S. research universities, technology transfer is the transfer of research results and the associated intellectual property rights to an organization or private company which will develop and sell final products and services, in exchange for royalties and, often, the funding of further research. Research universities fully realize that this perspective on technology transfer may lie elsewhere in other countries. In some countries, technology transfer generally refers to the acquisition of known production techniques; frequently, the acquisition "package" contains a strong training component.

Much has been learned by universities since the passing of the Bayh- Dole Act, and much remains to be learned. Legal and business tools, once alien to academia, such as patent applications, material transfer agreements, confidentiality agreements, distribution of royalties, *516 and others, have now appeared on university campuses. Today, most research universities have policies which guide the management of inventions, and include positions on ownership, disclosure, treatment of research sponsors and royalty distribution. However, new issues constantly appear and must be dealt with. For example, UIC recently approved a policy for the treatment of natural biological samples originating from developing countries. This policy includes the manner of sharing royalties with the country of origin.

B. Conceptual Bases of a Model System

1. Property

There is a general consensus in the U.S. that the mission of universities is public service through the creation of knowledge and the dissemination of such knowledge through teaching and publication. It is also generally agreed that universities should be free to choose their research topics and teaching methods. Many universities outside the U.S. also consider these goals as their mission. The intellectual property policies of individual universities reflect this basic philosophy while providing a means of protecting creative ideas and making them available to the public. Granting licenses to industrial companies is usually the most expeditious way of benefiting the public via university inventions.

Thus, with a few exceptions, such as Stanford and the University of Wisconsin, the policy of most U.S. universities is that work products developed through the university are owned by the university. Work products are defined as the results obtained by any person using university resources, such as laboratories, equipment, or funds controlled by the university. Work products can include research results, teaching tools, reports, data and lists of students.

Work products may be intellectual property, including: inventions (whether patentable or not); copyrights (except for "traditional" materials such as books, articles, notes and

artistic creations, as universities normally relinquish their ownership over traditional materials in favor of their author); and the research data itself, including the numerical data, graphs and tables. Alternatively, work products may be tangible property, such as synthesized chemicals, fractionation products, derivatives or cell lines, as well as the physical support of the experimental data, including laboratory notebooks, the graphic paper and files.

Universities also own inventions made by researchers working on their own time without the use of university resources, as long as the invention is in the area of research that the researcher is engaged in at *517 the university. This includes a researcher working on weekends in his or her own garage. Some universities, such as Yale, consider "traditional" material all that is protected by copyright, including software.

The ownership of work products secures future use of the products by the university for teaching and research purposes. Additionally, it allows the university to better protect its community and to handle potentially controversial matters. Thus, even though it is policy of the university that the researchers publish their results as soon as possible, a graduate student upon ending his studies cannot take his laboratory notebook, nor can he publish the data obtained during his thesis or dissertation research work without permission from the research supervisor acting in representation of the university. Also, no person from outside a university community can use the results that belong to a university until the data has been published and is in the public domain. By retaining ownership of data and its physical support, a university may be facilitating proof of an invention's date of conception in a court of law. This is very important if another person or organization intends to obtain a patent on the same invention. U.S. patent law rewards the first to conceive an invention and not the first to file a patent application as do most other countries in the world.

Universities also own trademarks. Typical cases involve the name and the logo of the university, which have great commercial value. This applies also to commercial brands associated with products of the university. One of the better known university developed brand names is "Gatorade," a drink whose formulation was developed by the University of Florida, and has a huge economic value. UIC developed and trademarked the vaccine "Tice," which is a bladder cancer vaccine that is used by a licensee, and produces a substantial annual income to the university through royalties.

The university should have the sole right to determine the disposition of university-owned work products, and normally will keep in mind the best interests of the university, the inventor, the sponsors of the research leading to the invention, and the public. Work products that have value may be handled in several ways:

a. Contact private companies directly, starting with the research sponsor if one exists; inform them of the opportunity; provide available information under confidentiality; and offer a license to the invention.

b. Transfer the invention to a patent management agency to carry out the technology transfer process, including *518 patenting, marketing of the invention, and negotiating and managing any licenses.

c. Assign invention rights to the inventor.

If the university does not retain rights, such as patents or copyrights, and the inventors or authors accomplished the work with the use of university resources beyond that which are normally provided, the university should retain, at a minimum, a royalty free non-exclusive right to use the research results for its internal teaching, research, and extension programs.

2. Reporting Obligations

In this paper the word "invention" will mean any work product that has a market value, and includes tangible and intangible property.

Inventors have a contractual obligation to report their inventions to the university and normally to the university's office of technology transfer. This does not mean that researchers have the obligation of inventing or of recognizing inventions, but they cannot benefit personally (nor can they allow others to benefit economically) from inventions based on their research without going through the university.

Researchers are encouraged to report their inventions to the university because benefits can accrue: (1) to society through new products and services; (2) to the university via new funds for the academic research sponsored by a licensee; and (3) to the inventor by additional personal income.

3. Royalties

The Bayh-Dole Act requires that the institution owning the intellectual property distribute a portion of the net royalties to the inventors. Net royalties are gross income less expenses directly attributable to patenting, marketing, licensing, protecting or administering the invention. Out-of-pocket expenses, such as payments to attorneys, marketing or licensing expenses, and expenses for the protection and administration of the invention therefore should be deducted from gross income.

The policy at UIC is to share 50% of the net royalties with inventors up to the first $200,000 of cumulative net income. Above $200,000, only 25% of the net royalties go to the inventors, while 75% stays with the university. When there is more than one inventor, the *519 inventors' share is divided among the co-inventors who are university employees as they mutually agree. Royalty checks are sent to inventors' private addresses, even if they have left UIC. University policies for sharing royalties with inventors can differ significantly. For example, the University of Colorado distributes 25% of its royalties and the University of Minnesota distributes 33%.

At UIC, 10% of the net royalties are given to the academic unit where the inventor resides and are used as discretionary funds in support of further research activities. The

Intellectual Property Office (IPO) retains the remaining 40% and enters it in three revolving funds, including:

a) A patent expense fund used to file and prosecute patents or to defend UIC's intellectual property against infringers;

b) An invention development fund to help inventors acquire additional data, develop prototypes to make the invention more attractive or enhance the credibility or value of an invention; and

c) An IPO management fund used to pay for services such as consultants, additional personnel for the office, or unusual expenses.

In contrast, at Yale University all net royalty income is transferred to the university's Provost, who distributes it for worthy research projects. For example, researchers who have difficulty obtaining outside research funds or young faculty not yet established in their field can use the support to acquire data or information that can be leveraged into larger grant applications.

There are cases in which the invention belongs to more than one organization. When collaborators from more than one institution have an invention, each one must assign their rights to the institution where they are employed. Since, according to patent law, the ownership of a patent is indivisible, each institution is owner of the whole patent and is free to manage it as it wishes. To simplify matters and for the sake of efficiency, the owners usually agree who will manage the invention, who reports to the government, and how the expenses and income are to be distributed.

*520 4. Research Agreements

Approximately 7% of national university research funds are provided by industry in the form of sponsored research agreements. Sponsors need data for their commercial and industrial purposes. This is perfectly acceptable, provided that university policies are observed. Thus, a university will not accept an obligation not to publish the results. Instead, universities may agree to postpone publication for a period of time, generally three months, to allow sponsors to review the results, consider new patentable elements, and allow time to file appropriate patents. Universities usually will not agree to conduct product development, but will instead focus on sponsored projects that foster basic research activities.

The objectives of sponsored research agreements are usually well defined in a contract where the sponsors identify their expectations and what they pay for. However, if the results reveal information that leads to unexpected inventions, they are not covered by the funds assigned to the contract, and should be paid for separately. The research contract normally gives the sponsor the right or option to negotiate a license for those kinds of inventions in exchange for royalties and other promises. This right is limited in time, generally three months from when the invention is reported to the company. If the company decides to exercise its option, then a license is negotiated within approximately

three months. If the company decides that it does not want a license, the university can offer licenses to any other company, including competitors of the sponsoring company.

If the research contract involves collaborations with a company, government laboratory, or other university, then the typical contract will state that the employee's organization will retain ownership of the inventions obtained exclusively by that employee. If there is more than one inventor, the owners will be those organizations which employ the inventors.

5. Material Transfer Agreements

Collaboration among researchers of various institutions is common and advantageous for all. This includes the transfer, for research purposes, of research materials of all types, such as chemical products, biological materials and novel equipment. Because some of these materials may have a market value, the use of "Materials Transfer Agreements" is becoming quite common. These are simple contracts that normally require the party that receives the material to:

*521 1) Use materials only for research purposes and not for commercial purposes;

2) Not give materials to third parties;

3) Not sue the owner because of any accident that occurs from the material's use;

4) Not use the material on humans; and

5) Either return the material to the owner or destroy it when the work is completed.

Material transfer agreements can be more complex when the transfer is to for- profit companies. If the demand for a useful research material is high, it may pay to license it to a distributor of research products for marketing, even if the royalty return is low, because the owner is freed from the tedious administration of distributing the material.

C. Management of the Inventions

The management of inventions varies among universities. Only a shrinking group of research universities, particularly small schools, contract the management of their inventions with external organizations. It is estimated that a technology transfer professional must be able to handle between 15 and 20 new inventions per year. If we assume on average that each $2,000,000 produces an invention disclosure, then hiring a full time manager is an important consideration for universities having at least a $30 million research budget.

The organization that has the most contracts for managing university inventions is Research Corporation Technologies (RCT) of Tucson, Arizona. RCT is a non-profit organization founded in 1912 to manage inventions of the University of California. Presently, RCT manages several hundred contracts and, in 1994, it received 671

invention disclosures and $59 million in royalties. The economic clause in a typical RCT service contract is that RCT retains 42.5% of the royalties for its administration and other purposes, and delivers 57.5% to the university. The principal complaint against RCT is that it chooses only those inventions that it estimates will be very successful. In *522 contrast, the UIC office manages inventions even when they promise only small returns.

Other universities are proactive in managing their inventions and carry out a full range of related activities. Among the proactive universities is a small group that emphasizes the creation of companies to exploit inventions made by the university. These are universities with large research budgets having the potential for many invention disclosures. In 1992, several of these leading universities were: Massachusetts Institute of Technology with a $324.5 million of research budget and 291 reported inventions; Johns Hopkins University with a $735.5 million research budget and 213 reported inventions; ARCH, which is an association between the University of Chicago and Argonne National Laboratory, with a combined $570 million research budget and approximately 100 reported inventions; and Harvard University with a $253 million budget and 87 inventions. [n3]

Therefore, one group of universities emphasizes licensing as the preferred manner of managing their inventions, while a second group promotes the creation of companies for selected inventions. UIC falls within the first group.

The Intellectual Property Office (IPO) at UIC consults with inventors so as to understand the substance of each invention. This discussion enables us to make preliminary evaluations regarding:

1) Patentability.
2) Commercial potential.
3) Ownership.
4) The sponsor's rights in the invention.

The first decision revolves around whether or not to administer the invention. If it is found that the invention can be protected, either through patents or through other means, and that it could be successful in the marketplace, then the IPO will agree to manage the invention. Otherwise, the IPO will offer to obtain the necessary permits to reassign the invention to the inventors. If the invention is relinquished to the inventors, the university will retain the rights to use it for internally *523 administered programs of teaching, research, and public service. In addition, the university will receive a portion of the inventors' eventual net earnings from the invention which normally constitutes the flip side of the distribution described supra.

The first step after accepting to manage an invention is to draft a brief, non-confidential description of the invention. This description should not reveal the patentable aspects of the invention which have not yet been protected, rather it should include potential applications and advantages over existing similar products or processes. The document also discloses whether a patent application has been filed and indicates what data is available and what remains to be done.

Then, utilizing various databases, books, catalogs and library holdings, a list is drafted of companies potentially interested in developing and selling final products and services based on the invention. The names of key officers are located and they are informed of the opportunity. Contacts in the companies are, preferably, those responsible for alerting the company of new external developments. This includes business development managers or licensing directors, research managers, vice presidents of engineering, or even the president of the company. Companies that are interested usually answer quickly requesting more information. The value of a particular invention can be measured by the speed and the number of responses to solicitous mailings.

The general strategy is to postpone patent filings until it is determined that there are reasonably good chances that the expense of $6,000 to $10,000 per application and an equivalent amount for the prosecution will be recovered. Other universities patent inventions before starting the marketing process to protect the property of the invention and allow a more detailed disclosure in their brief descriptions. The UIC's IPO considers this method onerous since it is estimated that only an estimated 15% to 20% of the inventions disclosed earn a royalty. Those inventions that generate funds average $23,000 per year. However, some universities have budgets to patent a great number of inventions. The UIC prefers to protect its inventions with secrecy laws. This is considered almost as effective and useful as the patent law. In our experience and that of our colleagues, there have been few problems with this protection. This strategy may be changing, however, with the onset of the provisional patent application.

When a company requests more information, UIC first negotiates and signs a confidentiality agreement before providing it with any additional information. This information circulates within the company among the researchers, the marketing department and the legal office, and is evaluated for scientific and marketing merit, and for the value of the legal protection of the intellectual property. The attractiveness of *524 UIC's system is that the whole evaluation is made by professional scientific, marketing and legal personnel who work precisely in the area of the invention and are presumably the most qualified to make a decision. Some universities establish faculty committees, or committees of local professionals or of entrepreneurial alumni to evaluate the inventions before launching them to the market. However, none of these groups are as acquainted with the specific area of an invention as the people who deal with similar products in a company. Therefore, UIC's method of evaluation appears to be more effective.

If a company is interested in producing and selling products or processes from an UIC invention, the IPO negotiates a license for the rights that protect the invention. Normally, in the license negotiations, we ask for several key things. First, a licensee must pay the patenting expenses of the invention if a patent is required to protect the invention. When an invention is patented, the prosecution is supervised by the university. The licensee always has the right to recommend prosecution strategies, which the university will evaluate but is under no obligation to execute.

Second, the IPO asks that the licensee sponsor research projects in the laboratory of the inventor, since additional data is almost always required before a product can be launched into the market. Third, a royalty structure is proposed. Finally, we request aggressive due diligence to take the product or services to market.

Frequently, situations do not adjust to this model because of special characteristics of the invention or unusual circumstances that arise. We then use appropriate variants. For example, the research sponsor has rights to the invention and exercises these rights. In this case there is no marketing, but we go directly to the negotiation of an agreement. Sometimes there is little time for marketing an invention because of a patent bar date. Then, one must make the decision immediately whether to patent, abandon, or reassign to the inventors. Also, the IPO can make the decision not to patent, and thus, to accept the loss of patent rights in certain countries. This decision allows time to do exhaustive marketing in the U.S. and to determine whether or not to patent the invention during the grace period.

It is important to note that UIC's policy is to never ask the inventor to postpone a publication. Together with the teaching and public service, publishing is a faculty member's most important function in the university. The IPO will mold its management strategy around the limitations imposed by publications or other public presentations. The marketing process can take weeks and up to a year or more, during which it is almost always necessary to consult with the inventor. If, after several months of marketing an invention (usually an average of 9 *525 months) no company has shown interest, the IPO will cease being proactive. If the inventors then wish to obtain the rights to the invention, the IPO will take necessary steps for reassignment.

D. National Associations

With the expansion of technology transfer activities in universities, a new hybrid professional has developed, the manager of technology transfer with a specialization in academic centers. There is an association of these professionals called the Association of University Technology Managers (AUTM), which has more than 2000 members. AUTM has national and regional meetings through which important contacts are made among colleagues and with representatives of companies, where new developments are discussed and debated, including legal topics, governmental policies, marketing, and negotiation techniques. AUTM has its own professional journal, and a page on the World Wide Web. There is also an e-mail discussion list called Techno-L, where information is exchanged and discussions are generated. AUTM also offers introductory and advanced courses on invention management.

Another organization, the Licensing Executives Society, is mostly made up of licensing professionals from private companies, but includes academic members. Finally, there is the Technology Transfer Society, whose members work mainly in government organizations.

E. License Agreements for University Intellectual Property

1. Background

Currently, most major American research universities have their own technology transfer programs to manage their intellectual property. These programs operate within the framework of the fundamental mission of the individual universities regarding creation and dissemination of knowledge for the benefit of society. Consequently, licenses for the intellectual property rights of university work products tend to distance the university from management decisions of the company and focus on furthering research at the university, on teaching and publishing, and on diligence by the licensee for rapid and efficient launching of products to the market. University technology transfer programs have had important repercussions on the university community.

In the past, numerous inventions made in the course of sponsored research were published in the scientific literature with very limited *526 efforts to protect them with patents. The few patents that were registered, were, by law, the property of the federal government. Their administration by federal funding agencies was complex and confusing, making them difficult for industry to access. Thus, in the 1970s, less than 4% of these patents were licensed. Since most university research funds were grants from the federal government, so few inventions were owned by universities that they could not justify a significant investment in technology transfer. With few exceptions, these inventions simply were not managed efficiently.

At present, it is generally accepted that universities, as employers, own most of the work products of their personnel. Even though most of the research results are dedicated to the public through publication in professional journals, the ownership of intellectual property rights, tangible materials, and unpublished information is held by the university. Thus, the university owns:

. inventions obtained in the course of research;
. newly developed software;
. prototypes built;
. synthesized chemical compounds;
. biological materials produced or discovered; and
. the data, results, and physical support of these data.

Most universities relinquish to the authors the copyrights to "traditional" materials including books, articles, notes, artistic creations, and teaching aids.

Universities manage their intellectual property by protecting, marketing and negotiating them. Most universities offer and negotiate options and licenses, exclusive and non-exclusive, while some universities, such as Massachusetts Institute of Technology and the University of Chicago, prefer to emphasize the creation of start-up companies in which they retain an equity interest. However, these models are not absolute. Universities

favoring licensing also will, under certain circumstances, encourage company creation. Conversely, those emphasizing company creation also offer licenses.

Occasionally, intellectual property is sold and ownership is transferred. However, this is an atypical transaction since the university loses control over the eventual exploitation of that technology. For example, the technology may not be developed into final products or processes.

*527 This would be contrary to the intention of universities to create knowledge for the benefit of society. Another problem associated with the sale of inventions arises when the work is supported by federal funds and the funding agency must approve the transfer of ownership.

The road to the present situation was not without obstacles. Until about ten years ago, the prevailing thought in U.S. universities envisaged science as a pure activity that should not be stained with the profit motive. Therefore, the participation of universities in technology transfer programs was frequently questioned. "Why should universities protect inventions? Why not publish all research results thereby placing them in the public domain?"

Several factors motivated the gradual change and include:

. The concept has been widely accepted that, without exclusivity, many inventions would not become products. Often a company would find it difficult to invest significant resources to develop products or processes without the exclusivity provided by patents. This is what allows private industry to recover its investment. There is also a consensus that the mission of universities is to create and disseminate knowledge to benefit society. Consequently, protecting and licensing the university's intellectual property rights becomes part of this mission because it gives the public access to new products and services based on university results.

. Federal budgets for basic research are growing more slowly than the number and size of grant applications. For example, only about 12% of the new applications to the National Institutes of Health are approved and funded. Consequently, universities turn increasingly toward industry seeking research funds, either as research contracts or through technology transfer. Licensees often sponsor research to develop final products or processes in the laboratory of the inventors who are the experts in the field.

. The Bayh-Dole Act. An influential visionary group of people decided, after countless studies, debates, forums, interviews and statements, that the Act was beneficial for the nation and it was passed and signed into law. Universities gradually accepted this conclusion. The law stipulates that a university must decide whether to retain ownership of an invention otherwise owned by the government. If not, the government, through its funding agency, can grant ownership to the inventor. However, this alternative frustrates the traditionalist objections since it introduces *528 the profit motive and precludes donating inventions to the public. Furthermore, this alternative is less efficient. Inventors usually are not specialists in technology transfer. Nor do inventors have the required resources to protect, market and negotiate inventions, and thus, have less competence and credibility than do institutions. Moreover, if inventors administer inventions, universities

could still be dragged into litigation through potential mismanagement. Consequently, if university technology transfer is here to stay, it would seem preferable that it be managed organically and systematically by universities and not by academicians operating individually.

. There are many controversial cases regarding faculty members of prestigious universities who venture into the commercial development of their inventions while continuing with their academic obligations. University authorities evaluated these cases thoroughly and then allowed them to continue, albeit under certain conditions and procedures. These precedents offered a legitimization of the exploitation of university intellectual property and created a framework under which even extreme cases could be managed adequately.

. If a company or person should benefit economically from the results of university research, it is only fair that they share their profit with the university.

After the more prestigious universities decisively launched their technology transfer programs, others followed their examples. Even though many universities experience negative cash flows associated with technology transfer programs, examples of successful cases promise good returns in the future.

2. Negotiation of License Agreements

a) General Strategies

Like many universities, UIC's patented or patentable inventions, works protected by copyrights (such as computer programs), trademarks, biological materials, and data are marketed, and licenses are negotiated with interested companies via exclusive, co-exclusive and non-exclusive licenses and options. Also, for the appropriate inventions UIC will *529 negotiate the creation of start-up companies and will consider accepting equity in exchange for royalties.

Co-exclusive licenses are exclusive licenses with perhaps two or three licensees. Also, a technology can be licensed exclusively by fields of use. For example, a technology that deactivates certain genes can be licensed exclusively to an agricultural company whose business is plant seed development for its use on plants. It may also be licensed exclusively to a company making veterinary products for use on animals. In addition, it can be licensed exclusively to a distributor of research products, a manufacturer of products for human diagnostics, and a pharmaceutical company for human therapeutics.

Universities prefer to give non-exclusive licenses because it is more consistent with their mission of dissemination. More licensees translates into a broader distribution of the technology and, presumably, more extensive use. More often, however, exclusive licenses are awarded because university inventions are typically in very early stages of development. Much more research and development effort is required before thosetechnologies find their way into final products or processes. Companies that invest

large sums of money can recover those investments by excluding others from competing during the life of the patent.

Exclusive licenses granted by universities have certain characteristics that differentiate them from company-to-company licenses. One of the most important differences is that universities will zealously negotiate research support for the inventors. Licensees are often asked to sponsor at least a part of the research necessary to reach final products. Some universities are prepared to sacrifice a part of the royalties in exchange for significant research support.

Other important issues in negotiating licenses with universities are:

. Programs for product development. In order for a university to achieve its mission of using research results for the public benefit, it must assure licensees launch vigorous programs to develop products or services for the public as soon as possible. A company might pay for a license in order to suppress an invention. This can be accomplished by denying the invention to competitors or by placing it on hold to avert competition with one of their own products. This proposition normally is unacceptable for universities and is why their licenses include strong due diligence clauses.

. Another way of ensuring due diligence on the part of a company to develop products is through the appropriate scheduling of *530 payments. Most licenses have up-front payments due at the signing of the agreement with minimum annual payments that are required whether or not there are sales. Usually these payments begin after a period of time considered reasonable for the company to develop products.

. Patents. In the case of exclusive licenses, all expenses related to patents must be paid for by the licensee, including filing, prosecution and defense. This is considered to be part of the cost of doing business. The university retains the final word on all decisions concerning the prosecution. This is important in order to avoid diluting the value of a patent by the special interests, or the lack of interest, of the licensee.

Further, the defense of patent rights can be very onerous since litigation can easily cost several hundred thousand dollars, and may be an issue in negotiations. But this too is considered part of the cost of doing business. Without patent protection there may be no commercial opportunity. Consequently, licensees generally agree to defend the patents. Otherwise, the university could terminate the agreement and find a licensee who would defend the intellectual property.

. Royalties. Royalties with a license are most commonly based on a percentage of net sales. The rate depends on what is being licensed. They can range from 75% or more for a valuable software ready for distribution, to a fraction of 1% for products slightly improved by the licensed technology. It is difficult to determine an appropriate royalty, especially with early-stage technologies such as university inventions, which sometimes only are at the idea level. Since there are no fixed rules and the negotiation takes place in a market environment, each side tries to negotiate what the market allows. A general rule is that the owner of the technology should be able to capture approximately 25% of the profit of the exclusive licensee, and approximately half of this of the non-exclusive licensee.

The royalty structure of a typical exclusive license is:

. An up-front payment due upon signing the agreement;

. A royalty as percentage of sales;

*531 . A share of royalties from sub-licenses; and

. An annual minimum royalty.

One variant of the formula is to draft a royalty structure similar to agreements in the field of the technology. Public companies, which have shares that are openly traded, must allow access to the contents of their important license agreements, at least to those that could affect the value of the shares. These documents are studied and used to provide a guide for what constitutes "the norm of the industry."

The information in Tables I [n4] and II [n5] illustrate examples of royalty percentages for different enterprises. For instance, a "normal" royalty on net sales of a diagnostic product that has only been proven to work in vitro is between 2% and 6%. Vigorous competition in the diagnostic products business results in estimated profits of about 8% to 24% of the sales price. To capture 25% of licensee's profit, the royalty on net sales should be 2% to 6%. Similarly, for new research biological products the royalty should be from 1% to 5%.

These figures are only approximate indicators of the value of a technology. There are at least one hundred variables that should be taken into consideration in assessing the value of an invention. [n6] Some examples include:

. The protective power of the patent. Patents claiming compositions of matter are the most valuable because of broad protection; they cover any use of the patented composition. Also, infringers are easily spotted when the material protected by the patent appears in a competitor's product. Method patents, such as a novel chemical synthesis, or use patents, such as vitamin C treatment of the flu, are less valuable because it is difficult to prove infringement, or because the number of infringers is overwhelming. For example, how could Linus Pauling have prevented someone from taking vitamin C for the flu?

*532 . The historical performance of the licensee. A new company, without history of product development, sales, or capability of attracting capital is a greater risk than an established, capitalized company with vast marketing capability. In this case, payment is required for the additional risk.

. Intensity of competition. If competition is strong, profit margin is expected to be smaller. Therefore, the desired 25% to be captured by the licensor translates into lower royalties on net sales.

. The size of the market. A very small market may not sustain high royalties.

. The cost of required training.

. Risk of litigation. Due to the quality of the patents or the type of product, this cost may be high. For example, the uterine contraceptive Dalkon Shield bankrupted A. H. Robins, Inc., who paid more than $2.5 billion to plaintiffs, [n7] and the silicon breast implant may cost Dow Chemical and other producers many millions of dollars. [n8]

. Restrictions to the expatriation of royalties.

. The level of development of the invention. Inventions that require little expense to market attract higher royalties. For example, a goat antiserum containing certain antibodies useful for research was licensed to a distributor of research products. All that was necessary for the distributor to do was dilute the serum, bottle it, label it and sell it.

This provided a royalty on net sales of about 40%. Similarly, software to connect personal computers to mainframes was licensed for 25% of net sales because it was a final product that only needed to be downloaded. On the other hand, inventions that require substantial research and development efforts to obtain final products or processes, such as therapeutic products, tend to yield cash payments that reflect their degree of development toward final products. For example, upon licensing *533 a vaccine for Lyme disease, the licensee paid more than a million dollars, in several stages, because its efficiency and low toxicity had been demonstrated in animals.

Another form of compensation for intellectual property rights is equity, instead of royalties. Such remuneration can be realized when the value of the equity reaches a certain level and the university can sell it. These earnings can be large. ARCH, the organization that manages the intellectual property of the University of Chicago, recently sold its participation in a publications company, created by ARCH, for $26 million. This method of compensation is particularly useful when the licensee is a start-up or a young company that has limited economic resources for which payment of substantial amounts of royalties in cash would be strenuous. Even in this case, a combination of equity and running royalties is recommended, instead of only equity compensation.

b) Therapeutic Products

Therapeutic products are treated in a somewhat special way due to the strict approval process by the Food and Drug Administration (FDA). In these situations, the applicant must demonstrate that the product is not toxic and, furthermore, that the product is effective. To achieve this, a long process of laboratory and clinical tests must be carried out. First, efficiency and low toxicity must be shown in vitro with laboratory samples. Subsequently, toxicity and dosage studies are conducted in laboratory animals such as rats, mice, cats, dogs, or monkeys. If all these results turn out positive, then limited toxicity and dosage studies are carried out on humans (Clinical Studies I). Next, limited efficiency studies are conducted in humans (Clinical Studies II). Finally, broad studies on a large number of patients must be completed to demonstrate that the possibility of adverse reactions is minimal or non- existent (Clinical Studies III). The FDA approves the sale of new drugs only if all these results are positive.

These studies can last up to a decade and can cost millions of dollars. It is estimated that for each 10,000 candidate compounds only one new drug is marketed. It has also been estimated that the cost of placing this drug on the market, including research and development, is between $240 to $350 million. This figure also includes the cost of failed initiatives.

The royalty structure in licenses for therapeutic drugs is different. In these instances, a series of milestone payments are scheduled, in addition to up-front payments, running royalties on sales, and annual *534 minimum royalties. As specific stages are reached in the progress toward marketable drugs, the invention acquires more value. The additional

value is shared with the licensor by means of milestone payments. However, the risk is also shared and payments are made only if each milestone is reached. Examples of milestones are:

. Receiving an Investigative New Drug (IND) permit to start clinical studies;
. Beginning Clinical Studies II;
. Ending Clinical Studies III; and
. Receiving approval for a New Drug Application (NDA).

c) Other Methods of Calculating the Value of a Technology

If the indicators discussed above do not exist for a particular case, or if their application is difficult, other methods exist for determining the value of a technology. Other methods include:

. The cost of reproducing the invention. This method is applicable to research products including chemical reagents and biological materials. Frequently these materials are not protected by patents because: (a) they have a short useful life; (b) the total amount of royalties involved is small; and (c) it may be difficult to obtain patents for them. Therefore, a calculation is made of what it would cost a third party to make the product. That is the invention price since the client will save time and the risk of failure.

. The cost of research that originated the invention. This argument is usually not persuasive but in the absence of other arguments, it can be used.

d) Non-exclusive Licenses

Non-exclusive licenses differ from exclusive licenses in that:

. They lack the negotiating power to obtain research support in the inventor's laboratory at the university.

*535 . The royalty payments are approximately half of those commanded by exclusive licenses. Normally, there are no minimum annual payments.

. The expenses for filing, prosecuting, and defending the relevant patents are covered by the university.

e) Options

Options are short term agreements to assure access by a company to a particular technology, usually to give the company time for a thorough evaluation. Options can be exclusive if the technology is withdrawn from the market for the duration of the option. However, options are non-exclusive if the owner continues marketing the technology. There is an obligation to negotiate with the optionee, the party holding the option, if so requested. Further, if an interested third party makes an offer, the terms have to be disclosed to the optionee and, under equal conditions, there is an obligation to give the optionee the right of first refusal of a license.

The option represents an advantage for the company and a risk for the university, especially if the technology is withdrawn from the market. Therefore it has value, commonly of a few thousand dollars. The duration of an option may be from a few months up to one or two years.

f) Follow-up of License Contracts

Once a license agreement is signed one cannot lay back and begin to collect the royalties. Agreements must be monitored and managed to make sure that their provisions are kept by both parties. In addition, vigilance for the protection of the intellectual property must be constant. In some cases this can mean much work, time, and expense. At a minimum, the following activities need to be carried out:

. Patent prosecution and protection of the intellectual property.

. Follow-up of payments.

. Follow-up on product development. Sometimes one must write reminders, make threats, and even terminate the agreement.

*536 . Follow-up of other obligations of the license agreements such as sales reports.

3. Consequences for the University Community

The new focus on the exploitation of university intellectual property has had important consequences for the members of university communities and especially for faculty members.

Since the 1970s, largely due to the surge of biotechnology, some university researchers and inventors have participated in the commercial development of their own inventions by:

. Starting-up their own companies with their inventions.

. Accepting director or managing positions in companies which were licensees of their inventions.

. Accepting positions in scientific advisory boards of companies which were licensees of their inventions.

. Accepting substantial equity in companies which were licensees of their inventions.

. Accepting research projects sponsored by companies in which they held equity positions, and which were licensees of their inventions.

. Directing dissertations and postdoctoral projects on topics of interest to companies in which they held equity positions.

. Interfering with the academic activities of the university. In one case, a faculty member took the topic of dissertation of a student to his company so that it would be solved more speedily. The student in turn had to start a new project.

From the point of view of many academics, these activities are contrary to university ethics, even if they may have had positive aspects, including offering new opportunities to the university in research contracts, public relations, and recognition. Some of these

cases were scandalous and put the credibility and the public trust in the universities at stake.

*537 These problems along with the requirement of the funding agencies of the federal government who have legitimate concerns that federal funds be used for the public interest and not for private benefit, the major research universities of the country formulated policies to manage conflicts of interest and conflicts of commitment. These policies identify, manage, and eliminate real conflicts as well as attempt to avoid even the appearance of conflicts. These policies are different from those dealing with academic misconduct issues such as data tampering, plagiarism, misappropriation of data or projects, and other illicit or dishonest incidents, which have existed in universities for a long time.

A conflict of commitment exists when the external activities of a university employee require so much time that they interfere with the obligations to the university.

A conflict of interest exists when an employee is in a position to favor his own interests, or those of his family or friends, to the detriment of the university's integrity and mission. As a corollary, it is inappropriate for the university to accept obligations that limit the freedom of choosing research topics or research strategies. Also, it is inappropriate to accept the indefinite postponement of publications to satisfy secrecy needs of the sponsor of the research.

UIC has decided that some activities require prior written approval from the university before they are carried out. Examples of these activities are precisely those listed supra, which have been considered inappropriate by many academicians.

In addition to reporting these activities when they appear, all UIC professional employees must deliver an annual report indicating:

. Consulting or other financial relationships with each research sponsor;

. Managerial roles, directorships, or significant financial participation of more than $10,000 or more than 5% equity in a company in one's field of research, or that has business with the university; and

. External activities or business that involve university students or employees.

Among the possible solutions to these problems are the following:

. Modification of the research project;

. Appointment of an oversight panel or person to monitor the progress of the project, or student participation;

*538 . Sale of equity;

. Resignation to positions; and

. Leave of absence without pay.

Personnel who do not comply with the regulation could be sanctioned by a reprimand or dismissal. For tenured faculty, a complex procedure exists to deal with cases of dismissal.

II. CONCLUSION

Technology transfer activities in American universities are on the rise, and will be increasingly successful. Each year, more universities have technology transfer operations with positive cash flows. This trend will continue since many of the licensed inventions are in the development stage and will only produce royalties in the future. Furthermore, large companies have been cutting their budgets for basic research, and the possibility exists that their needs could be satisfied by universities. Finally, the repudiation expressed by academicians for these "impure" activities has abated, in good measure due to the policies enacted.

TABLE I: BIOMEDICAL LICENSING GRID

TECHNOLOGY CLASSIFICATION	RUNNING ROYALTY	UP-FRONT PAYMENTS	MINIMUM ANNUAL ROYALTIES	COMMENTS
Reagents or Process Method	1-3%	Recapture patent costs	$2 - 10,000	---
Reagents for use in Research Kits	2-10%	Recapture patent costs	$2 - 10,000	---
Diagnostics, in vitro	2-6%	$5-10,000, up to $20,000	$2 - 60,000	Sometimes a sliding scale for royalties is used
Diagnostics, in	3-8%	$5-10,000, up to	$2 - 60,000	---

vitro		$20,000		
Therapeutics	4-12%	$20-50,000, up to $150,000	(worst case sales scenario) x (base royalty rate) x (10 to 30%)	A sliding scale for royalties is often used
Medical Instrumentation	4-10%	$5-150,000	$5-20,000, 1st year $10-25,000, thereafter	---
Software	3-15%	up to $100,000	---	---

TABLE II: LICENSING-OUT ROYALTY RATES -- BY INDUSTRY

	Royalty Rate Category Distribution						
	0-2%	2-5%	5-10%	10-15%	15-20%	20-25%	> 25%	Total
PRIMARY INDUSTRY								
AEROSPACE	0	40.0	55.0	5.0	0	0	0	100%
AUTOMOTIVE	35.0	45.0	20.0	0	0	0	0	100%

CHEMICAL	18.0	57.4	23.9	0.5	0	0	0.1	100%
COMPUTERS	42.5	57.5	0	0	0	0	0	100%
ELECTRONICS	0	50.0	45.0	5.0	0	0	0	100%
ENERGY	0	50.0	15.0	10.0	0	25.0	0	100%
FOOD/CONSUMER	12.5	62.5	25.0	0	0	0	0	100%
GENERAL MFG.	21.3	51.5	20.3	2.5	0.8	0.8	2.6	100%
GOV'T/UNIVERSITY	7.9	38.9	36.4	16.2	0.4	0.6	0	100%
HEALTH CARE EQUIP.	10.0	10.0	80.0	0	0	0	0	100%
PHARMACEUTICALS	1.3	20.7	67.0	8.71.3	0.7	0.3		100%
TELECOMMUNICATIONS	0	0	0	100.0	0	0	0	100%
OTHER	11.2	41.2	28.7	16.2	0.9	0.9	0.9	100%

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