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LEGAL ASPECTS OF LICENSING OF TECHNOLOGIES DEVELOPED IN UNIVERSITIES AND RESEARCH INSTITUTES

A. Introduction

This is a "golden age" for Intellectual Property (IP). More than ever companies are built around patented technology. "Innovate or perish" is the motto. Patent filings and issuances are skyrocketing, so much so that there is talk of a patent "revolution", "explosion", "frenzy". The courts are pro-IP as is legislation; even the Antitrust Division of the U.S. Justice Department is pro-IP. In their joint 1995 "Antitrust guidelines for the Licensing of Intellectual Property", the Justice Department and Federal Trade Commission profess up front that 1) "intellectual Property (is) comparable to any other form of property", 2) there is no presumption that "intellectual property licensing creates market power" and 3) "intellectual property licensing…is generally pro-competitive"? This was an 180-degree turn when contrasted to Justice's prior hostility to patents, culminating in their philosophy that a patent conferred monopoly power as a matter of conclusive presumption and at least nine common licensing restrictions ("nine no-no's") were per se illegal!

Courts read the riot act to infringers. Billion dollar damages have been awarded. Treble damages, once rare, are now the order of the day. Injunctions are normal and not even stayed during appeals.

"Everything under the sun made by man" is patentable according to our Supreme Court. As of 1998, formerly unpatentable business methods and computer programs (algorithms) are now also patentable.

Royalties obtained for licensing IP have reached the billion dollar mark for companies such as IBM, TI. Hence, IP rights are most valuable corporate assets, crown jewels.

And universities, not to be left out, have jumped on the bandwagon. (The term "universities" includes teaching hospitals and other not-for-profit research institutes.) Some statistics will illustrate this.

1. In 1997, for example, universities received 11,303 invention disclosures, filed 4,267 new patent applications and issued 2,645 patents. In 1998, the ten top patent-receiving universities were University of California (395), MIT (138), University of Texas (98), California Institute of Technology (93), University of Wisconsin (83), Stanford University (79), Johns Hopkins University (79), University of Pennsylvania

(69), Michigan State University (59), and Cornell University (55). And unsurprisingly these are among the most successful of the universities engaged in licensing the inventions made by their faculties, graduate students and staffs.

2. According to a recent AUTM survey (Licensing Economics Review, February 1999, p.11), in 1997 universities held 15,238 active licenses with corporations, with over 3,000 granted in 1997 and with 70% in medicine, disease diagnosis and pain reduction. (*Id.* at 12.)

3. More than 1,000 commercial products have been developed and licensed by universities, bringing 250,000 jobs and $30 billion into the U.S. economy annually, according to the same survey.

4. The amount of money universities reap from patent licenses is soaring. Annual patent royalty revenues rose from $275 million in 1995 to $576 million in 1998, with a couple of universities garnering over $100 million.

5. For example, the University of Wisconsin milked over $100 million in royalties out of their Vitamin D research and the anticancer drug, Taxol, has brought over $100 million ($51 million in 1998 alone) to Florida State University under license to Bristol-Myers Squibb Co., with the inventor of a synthetic manufacturing process for it receiving millions.

   Stanford has been one of the most successful universities in recent years in generating royalty income. In 1997-1998, the Office of Technology Licensing generated $61.2 million total, with 28 inventions out of 298 technologies which paid royalties in 1997-1998 generating more than $100,000. Fourteen inventions generated more than $200,000. Most of the inventions generating over $100,000 were at least 10 years old, with the basic DNA cloning patents generating $37 million.

   And MIT in 1998 raked in $20 million in invention-related royalties and has sponsored 140 companies since 1987.

6. Another indicator of the growth and importance of university innovation and technology transfer: In 1980 SUPA (Society of University Patent Administrators) had 65 members and in 1998 AUTM (SUPA renamed) had over 2,200 members. The number of universities with technology transfer programs increased from 30 in 1972 to 275 in 1997 and according to Lita Nelsen of the MIT Technology Licensing Office "almost all research universities in the U.S. have technology licensing operations" now. And these operations hire patent and licensing professionals left and right.

B. <u>Ownership of University Inventions</u>

1. The Common Law Principles

In the U.S., long established common law principles grant to employees, such as, university faculty, the inherent right of ownership to their inventions. Ownership follows inventorship. However, this inherent right is abrogated if an express contract to that effect exists.

The U.S. Supreme Court decision in *U.S. v. Dubilier, 289 U.S. 178 (1933)* is the seminal case in this matter. The applicable common law principles to determine the status of employee-generated inventions, which were enunciated by the court in this case, have been applied to a wide spectrum of employment settings. This case involved the rights of two employees of the Bureau of Standards of the U.S. Department of Commerce. Francis Dunmore and Percival Lowell were two full-time researchers in the Bureau's airplane radio group of the radio section of the electrical division. During the course of their work the researchers invented three products in a area they had been working on out of scientific curiosity. Their work in this area was voluntary. However, they pursued their research while on duty using Bureau resources and time and with the full knowledge of their supervisors. *Dubilier* asserted that the proprietary rights in the invention are vested in the employer only if the employee is specifically "hired to invent". It is interesting to note that the doctrine of hired-to-invent has generally been circumscribed by the courts' reluctance to read it too broadly. As a rule an employee is considered as hired to invent only if the invention falls clearly within the scope of the contract. In fact, the burden is on the employer to prove that the employee was hired to create a specific invention.

This attitude of the courts is reflected in the decision of the Superior Court of Florida in *State Board of Education v. Bourne, 150 Fla. 323 (1942)*. The court upheld the rights of the inventor to his invention on the grounds that the employee was a part of the research team as a plant pathologist and was not hired as a geneticist. In brief, if the individual is hired for the purpose of conducting research, he does not loose the right to his inventive idea unless he is assigned to the specific area in question. Dissenting with this general trend the Supreme Court of North Carolina in *Speck v. N.C. Dairy Found., 307 S.E. 2d 785 (N.C. 1983)*, held that university faculty employed as "teachers and researchers" fall within the category of persons "hired to invent" and thus do not have a right or interest in inventions arising from university research. This opinion is significant to the extent that it is the first case where the issue directly addressed involved the respective rights of the faculty inventor and the university.

If in the creation of the invention the time and resource expended was that of the employer, a non-exclusive license or a shopright in the invention arises in favor of the employer. Thus, as far as the common law is concerned the question of employee invention turns on two critical factors:

a) whether the research/invention falls within the scope of the work responsibilities of the employee and

b) whether in the creation of the invention resources of the employer were used.

2. The Practice for Non-government-sponsored Inventions

. The contractual agreements that characterize the employment relationship between universities/research institutions and the faculty, are increasingly molded by the general policies of the universities/research institutions, which presume institutional ownership of faculty-generated invention/research. This trend is predicated upon three factors which seem to be pushing the universities towards entrepreneurial activities. These factors are:

a) government incentive for creating innovative technology in collaboration with industry,

b) cooperation and inducement by industry, and

c) the self-interest of the institution.

These entrepreneurial opportunities are compelling universities to formulate policies in order to resolve the perplexing issues surrounding faculty ownership rights in inventions and research results.

A brief survey of the policies followed by different universities reveals that while the language may differ, the basic considerations behind these policies is the presumption of ownership by the universities. The basis on which ownership is claimed can be classified into three basic approaches:

a) ownership claims based on utilization of university resources or facilities,

b) ownership claims if the invention is developed in the course of employment, and

c) ownership claims which are made irrespective of whether the invention was made by the faculty using university resources or during the course of employment.

3. The Policy Claims for University Versus Faculty Ownership

The policy invoked by the universities to substantiate their claim to ownership of faculty-generated inventions cover a broad range of arguments involving issues of competitive business practice, federal government requirements, legality of the policies, existence of infrastructure for useful exploitation of university inventions, etc. At the heart of the matter is the question of the revenue-generating possibilities of the inventions, the issue of entrepreneurial opportunities which may arise from inventions, and their broader implications on the financial health, reputation, ability to attract talent, and resources in a highly competitive marketplace of the universities.

Faculty ownership of university-created invention, on the other hand, it is argued, rests on the assumption that ownership will act as a catalyst to enhance the faculty's creative genius. The policy claim for faculty ownership of invention is predicated primarily on the argument that university ownership of faculty inventions will eventually endanger the academic mission of the university concerned, namely, that it

would jeopardize university emphasis on basic research by countenancing allocation of resources towards applied research.

4. The Practice for Federal Government-sponsored Inventions

Before the enactment of The Patent and Trademark Amendment Act of 1980 (35 U.S.C.A. ss 200-211, ch. 18 (West 1980); 37 C.F.R. ch. 4 pt. 401 (1989); 45 C.F.R. ch. 6 pt. 650.) — known as the Bayh-Dole Act — no uniform regulations governed ownership rights between a sponsoring government agency and the university contractor receiving the funds. The Bayh-Dole Act, envisages that in the eventuality of an invention flowing from the research sponsored by a government agency, the university elects title to the invention while the government acquires a non-exclusive, nontransferable, irrevocable, paid-up license. If the university does not elect to take title, the government may claim title. If the government does not claim title, then the inventor may petition the government agency for ownership, which is usually granted. The law applies to all federal agencies and virtually to all federal funding agreements with universities.

So-called "march-in rights" may be exercised by the government agency if (1) the agency determines that commercialization of the inventions is not being effectively pursued; (2) the license is necessary to satisfy health or safety needs; (3) the patent holder has not met the public use requirements specified by federal regulations; or (4) the patent holder has failed to agree that products incorporating the patent invention will be manufactured substantially within the U.S.

Other key provisions of Bayh-Dole, which turned out to be a truly impactful, trailblazing piece of legislation, are that the university

- generally may not assign an invention to a third party,
- generally must give priority in licensing to small businesses,
- must ensure that any exclusive licensee of the invention in the U.S. manufactures substantially in the U.S. and
- must share a portion of royalties with inventors and use the balance for scientific research or education.

According to Lita Nelson of MIT, "the phrase 'Bayh-Dole' is heard frequently in Japan and Germany as their educational ministries seek to emulate the U.S. university technology transfer system." (Science, March 6, 1998). Indeed, in Japan the "Law on Special Measures for Industrial Revitalization", a law that is comparable to the American Bayh-Dole Act of 1980 and commonly referred to as the Japanese Bayh-Dole, went into effect on October 1, 1999. And Japan universities are beginning to collect royalties, e.g. Tokai University's recent take of $0.5 million.

C. University/Industry/Government Interface

1. Nature of University/Industry Research and Research Funding

Research funding through grants and contracts is an important source of funding for universities. According to Katharine Ku, Director, Office of Technology Licensing, Stanford University, "(r)esearch in most universities in the US is funded 85-95% by the US government: at Stanford, for example, the US government funds approximately 85% of the $327 Million research effort: $283 Million Federal government funding, $44 Million non-Federal funding and of that non-federal funding, $13 Million comes from corporations." (Katharine Ku, *University — Industry Links; Licensing; Technology Transfer Arrangements; Research and Development*, WIPO Asian Symposium Lecture, New Delhi, January 1992, WIPO/INNOV/DEL/92/4) However, Pat Chew would take issue with this figure, saying that it is only 50%. (Pat K. Chew, *Faculty-Generated Inventions: Who Owns The Golden Egg?*, 1992 Wis. Law Rev. 260.) At any rate Government funding is going down and corporate funding is going up.

Typically, if a company supports research at a university, Katherine Ku indicates "the company is generally able to receive certain rights to inventions that come out of the research. A company also has the right to review publications and to ask for a specific commitment in terms of personnel effort within a general work statement. Research at most universities, however, must be open because the principle of freedom of access to the underlying data is of overriding importance." (*Ibidem.)*

Many universities do not wish to become a research arm of a corporation and do mere product development. But if there is true research to be accomplished, most universities are eager to collaborate with industry. Many companies have established major research agreements with universities in the hope and with the expectation that such collaboration will be beneficial for both parties, especially in recent years and in the field of biotechnology.

Corporations tended to be reluctant to deal with universities until about 15 years ago primarily because university research often was touched by federal grants as federal funding was very prevalent and ownership often in question. Freedom to use such an invention exclusively was out of question until fairly recently.

As already intimated, universities in general do not undertake what is usually referred to as "contract research", that is, as pointed out by Joyce Brinton, Director of the Office for Technology and Trademark Licensing of Harvard, "research done at the university is presumed to have scholarly or academic importance and that will lead to new insights into the science. Carrying out a project that is designed and directed by a sponsor is not generally appropriate. Perhaps the closest thing to contract research is the conduct of clinical trials, and the rationale for participating in them is the ability to provide access to new treatment modalities and thus be at the cutting edge of clinical practice." (Joyce Brinton, *IP Rights in Non-profit Institution Contracts (Why do those universities behave the way they do?)*, American Bar Association Section of Patent, Trademark & Copyright Law, 1993 Annual Meeting Education Program Materials 707, 708 (1993)).

2. University Policies — The Harvard Paradigm

What rights will universities grant research sponsors? If the sponsor has the resources and capability to rapidly develop and market products based on the likely results of the sponsored project, most universities will grant the sponsor the opportunity to obtain exclusive commercial license rights. There was a time when many universities would only offer non-exclusive license rights. Over time, that position has changed, but there are still situations when the commitment of exclusive rights may not be appropriate, e.g. general techniques for gene-splicing a la Cohen-Boyer patent.

Universities require as a matter of general policy that inventions made by their employees be assigned to the university and not to the sponsor. This is also a requirement of federal law when there is federal funding co-mingled with corporate research funding. Inventions made jointly by employees of the university and employees of the sponsor are frequently owned jointly but still are governed by the sponsored-research agreement.

The next question is who pays for patent solicitation? Brinton provides the following answer:

> "When an investigator reports a possible invention to the university, or the university or the sponsor determine an inventions is disclosed in a manuscript or abstract reporting on the sponsored project, the sponsor is given an opportunity to decide whether it wishes a patent application filed. If it does, the sponsor is generally expected to support those patent filing costs. Because the university has limited funds available for filing patent applications, it cannot be placed in the position of being required by a sponsor to file patent applications at the university's own expense. On the other hand, if the sponsor decides not to support the filing of a patent application and the university decides to proceed at its own expense, the sponsor would no longer have rights to that invention." (*Id.* at 711.)

Regarding the further question as to who handles the patent prosecution, Harvard's standard license clause provides that Harvard will arrange for patent counsel of its choice and that the sponsor will be consulted at all stages of drafting, filing and prosecution. This is critical since the company will be in a unique position to insure that the application will be sufficient to protect the type of product the company has under development.

Harvard even permits the sponsor to select a patent counsel or even use its in-house patent counsel but the outside attorney must understand that Harvard is the client rather than the sponsor. If the sponsor's internal patent counsel is used in order to take advantage of his/her special expertise in the particular field, Brinton feels that in that case Harvard's own counsel must approve all actions. This is important to avoid potential conflicts of interest. As all this is done at sponsor's expense, it would be this author's suggestion that the sponsor should insist for its own protection on a cap on expenses, however.

Harvard's interesting contract provisions in this respect are as follows:

> The parties agree that it is desirable to file applications for patents on discoveries and inventions conceived and first reduced to practice during the term of this Agreement by personnel of HARVARD (including faculty, students and employees) in the performance of the Research. HARVARD agrees to report to SPONSOR such discoveries and inventions as are disclosed to HARVARD and to cause patent applications to be filed and prosecuted in its name at SPONSOR's request and expense on such inventions as may in SPONSOR's judgment become appropriate during the term of this Agreement. All information given to SPONSOR by HARVARD in accordance with this Section shall be held in confidence by SPONSOR so long as such information remains

unpublished or undisclosed by HARVARD. Such patent applications and any patents resulting therefrom shall be subject to the terms of the Agreement.

HARVARD shall have the opportunity to file patent applications in its name at its own expense for those inventions made by its personnel and for which SPONSOR does not agree, within thirty (30) days after notification by HARVARD of its intent to file a patent application, to pay for HARVARD to file said patent application; such patent applications and any patents resulting therefrom shall not be subject to the terms of this Agreement.

The next point to consider after patent filing is how rights are conveyed to the sponsor. Harvard's policy is to grant the sponsor an exclusive, time-limited option during which the sponsor can evaluate the technology, and then a subsequent period in which to negotiate the terms of a license agreement. Without such a time limit, the technology could be tied up indefinitely without any development efforts taking place. This policy is reflected in the following contract clause:

HARVARD, to the extent it is permitted to do so by its "Statement of Policy in Regard to Inventions, Patents and Copyrights" dated March 17, 1987 ("Patent Policy"), by its agreements with other sponsors of research, and the provisions of Public Laws 96-517 and 98-620, grants to SPONSOR an exclusive option to negotiate world-wide licenses under patent applications filed pursuant to this Agreement and under any resulting patents.

Such option with respect to each patent application shall extend for a period of _____ days from the date SPONSOR receives notification in writing of the filing of such patent application and a copy of such patent application, which notice and copy shall be sent to SPONSOR by HARVARD promptly upon filing. SPONSOR may exercise its option on HARVARD's patent applications or patents by informing HARVARD of the identify of such patent application and by providing a written statement, satisfactory to HARVARD, of its capability and intention to develop the invention (either alone or in conjunction with others or by means of sub-licensees, as appropriate) for public use as soon as practicable, consistent with sound and reasonable business practices and judgement. Upon exercise of each such option, SPONSOR shall have months to negotiate the terms of a license agreement and HARVARD agrees to negotiate these license terms in good

> faith. During the option and subsequent negotiation periods, HARVARD shall not offer commercial license rights to any third party. At the end of this time period if no license agreement has been signed, HARVARD shall be free to negotiate licenses with other parties.

Obligations to other sponsors can occur due to collaborations as well as due to co-mingling of funding for a particular project. Harvard wants to "preserve the right of their faculty to collaborate with other scientists. And if that collaboration results in a joint invention, (they) want to recognize the rights of the sponsors of all the joint inventors. Obviously, that means true exclusivity is impossible. If collaboration is anticipated ahead of time, it is possible to negotiate a sharing of rights among the sponsors, but if it occurs spontaneously, (they) want all parties to understand that they will be limited in what they can deliver in the way of license rights." (*Id.* at 714.)

In other words, such university/industry research agreements should reflect a win/win approach and outcome.

Harvard's relevant contract provision is as follows:

> It is understood that the HARVARD investigators shall be free to discuss the Research with other investigators and to collaborate with them.
>
> Notwithstanding HARVARD's commitments regarding intellectual property in this Agreement, in the event any joint inventions result from such collaboration, HARVARD shall grant to SPONSOR the rights outlined in this Agreement to the extent these are not in conflict with obligations to another party as a result of the involvement of other inventor(s). In this latter case, HARVARD shall exert its good faith efforts to enable SPONSOR to obtain rights to the joint invention.

D. Model Agreement for University/Industry Cooperative Research

As can be seen from the few select Harvard contract clauses rendered above, Harvard has a highly developed and comprehensive policy and practice in this area. This should not come as a surprise. Other large research-oriented universities have had similar policies and practices in place for many years. The most sophisticated policy and practice is that of MIT which, in fact, is so special that its written embodiment, a thirty-page document called "Guide to the Ownership, Distribution and Commercial Development of M.I.T. Technology", is "For Internal MIT Use Only".

However, the Industrial Research Institute and the Government/University/ Industry Research Roundtable have jointly developed and published a very useful and handy

brochure entitled "Simplified and Standardized Model Agreements for University-Industry Cooperative Research" (National Academy Press, Washington, DC 1988) with the expectation that these models would be useful as starting points for negotiations, streamline the negotiation process and decrease the time and effort required to reach an agreement. Quite possibly, such models may be more helpful and suitable than the overly polished MIT paragon.

The two models presented are reproduced as Appendices, namely, a simple research grant between universities and companies for basic research support and a more elaborate, but still simple and standardized, research contract with a few optional and alternative clauses — all of which is straight-forward enough to speak for itself. A caveat is expressed to the effect that "they are not intended to serve as a final document." Indeed, caution is always in order with respect to model and boiler-plate provisions as they may not fit all situations — a point which this author never tires of emphasizing in teaching Licensing /Technology Transfer.

In the Preface to this brochure it is also pointed out very aptly and fittingly that these model agreements "represent a reasonable approach to university-industry research agreements...based on the notion that research agreements should reflect the interests of both parties." The hope is also expressed that "both universities and industry will approach research undertakings with a degree of flexibility and creativity, taking into account the special interests and needs of each other." In other words, such university/industry research agreements should reflect a win/win approach and outcome.

E. Problems and Pitfalls in Industry/University Research Relationships

First and foremost, there are potentially serious publication problems and impasses. On the one hand, since dissemination of research findings is at the core of academic life, the university position is fairly straightforward: the investigator must be able to report the results of his/her research without undue delay and without censorship by the sponsor. The sponsor, on the other hand, may be concerned about a potential loss of intellectual property rights and thus may want the right to delay publication until patent applications are filed or may even want to preclude publication in order to main the results as a trade secret.

This is one of the areas, where there is considerable variation among universities. According to Brinton:

> "Harvard, is at one of the extremes...Harvard will allow no delay in publication and will not even guarantee that the sponsor will receive copies of publications prior to their submission for publication. This may sound as though it would jeopardize foreign patent rights, but in actuality, it need not do so."

> "First, if the sponsoring company and the investigator are communicating — as they should be — throughout the research project, the company will be aware of results well before a publication is even drafted, much less submitted for publication. And if there is actual collaboration between the university investigator and a company scientist, that sort of communication is assured. Then, if the research yields something on which patent applications should be filed, the patent application and the publication can be prepared in parallel." (*Id.* at 709.)

Harvard's relevant contract provision on this point is as follows:

> HARVARD's Investigators have the right to publish or otherwise publicly disclose information gained in the course of the Research. In order to permit SPONSOR an opportunity to determine if patentable inventions are disclosed, the Principal Investigator will provide SPONSOR with copies of articles written by project personnel reporting on the Research prior to or coincidental with submission for publication. Whenever possible, efforts will be made by the Principal Investigator to provide drafts of intended articles as soon as they reach a stage suitable for distribution. SPONSOR shall inform HARVARD and the author(s) in sufficient time so as not to delay publication whether in its judgment the material contains information on which patent applications may or should be filed. HARVARD and SPONSOR shall inform the Principal Investigator of the effect on patent rights of the disclosure of patentable information prior to the filing of a patent application.

Even if there is no communication and the copy of the submitted publication is the first time the company learns that a patentable invention has been made, it usually takes about four to six months before the article is actually published. During that time period, it should be possible for the parties to decide whether a patent application is to be filed, and to get it filed. Even if the publication is on a "fast track", there are at least three weeks to get an application on file.

That is Harvard's view but it is not that simple in this author's opinion who had run into situations in his previous career as corporate patent counsel where he had to file patent applications within a day for university professors whose inventions of interest to the corporation had been published and the one-year grace period was running out. The ready availability of the journal text made it possible to still file an application in the "final hour." However, foreign patent rights were lost. Also, submission of the manuscript to the editor and to peers for peer review may pose a risk to patentability.

And then there is the problem with oral disclosure. Presentations at scientific meetings can constitute a bar to patent filings in absolute novelty countries. "Fortunately", according to Brinton, "most major scientific meetings require the submission of abstracts well in advance of the meeting and those abstracts will enable the sponsor and the university to decide whether a patent application should be filed. If an abstract is not submitted in advance, a possible solution is to require that the investigator notify the sponsor when he/she accepts an invitation to present the results of the sponsored project. Then, the sponsor and the university can review the work in progress and prepare a patent application if appropriate." (*Id.* at 700.)

Also there is a tendency of scientists to discuss their research findings with colleagues at, e.g., the Gordon Conferences, well before either submitting an article for publication or before making a presentation at a scientific meeting. There could be potential loss of patent rights through this route. There is certainly no way the university or the sponsor can monitor these informal conversations. To do so would be to intrude in an unacceptable way in the normal discourse of science. Besides, there is supposedly an unwritten convention among scientists that the sharing of unpublished research is "confidential." Anyone who published those results before the provider would be censured by the scientific community. Nonetheless, company scientists can get insights into what competitors are up to.

Another conflict-of-interest area, according to Katharine Ku and as stated in Stanford's "Faculty Policy on Conflict of Commitment and Interest", is the following: Universities want faculty and researchers to conduct research objectively without influence by personal financial gain.

> (F)aculty owe their primary professional allegiance to the university and their primary commitment of time and intellectual energies should be to the education, research, and scholarship programs of the institution. Students should be able to learn independent of the personal commercial interests of their advisors. University facilities should be used for university purposes, and not for outside activities.
>
> For technology transfer reasons, it is often desirable that the faculty work closely with the licensee. for conflict of interest reasons, this 'closeness' sometimes presents a concern. Most universities have a process to review conflicts of interest and are able to find ways to balance the interests of the university to have the researcher conduct objective research against the licensee's interests to have the researcher 'invested' in the company. (Katharine Ku, University Licensing and Technology Transfer, The Licensing Journal, May 1999, p.13)

Start-up companies harbor a specially challenging conflict-of-interest problem, according to Katharine Ku.

> Universities are often willing to take equity as partial compensation for a license agreement since start-up companies are typically cash-poor. University licensing offices have also seen start-up companies as an effective vehicle for early stage inventions. These companies license an invention from a university, develop the technology to a certain stage, and then partner with larger companies that can bring experience, resources, and marketing know-how to the smaller company.

MIT does take a small percentage of equity in start-ups "in partial lieu of royalties", in addition to some licensing fees and some running royalties, but without playing any management role. Also MIT inventors can take equity in start-ups but may not accept sponsorship of research by that company.

On this point, MIT's "Conflict Avoidance Statement" is of interest. See Appendix I.

There are other problems and pitfalls. A very troublesome one comes to light in so-called derivation interference proceedings. An interference in the U.S. first-to-invent patent system is a contest where two or more patent applications pending in the U.S. Patent and Trademark Office (PTO) claim the same invention and a determination must be made as to who is entitled to the patent, inasmuch as only one patent can be issued on one invention. An interference can be either a contest to determine priority or originality. In the former, the respective dates of conception and reduction to practice of an invention are taken into consideration to decide who made the invention first. In the latter, a derivation contest, the issue to be decided is who made the invention.

For instance, in this author's professional experience, it happened several times that a university, to whom an inventive concept or invention was disclosed to enable it to carry out certain tests to complete reduction to practice or to confirm the utility, filed a patent application on such an invention incorporating their test results before they were communicated to the corporate sponsor and without informing it of such filing. Subsequently, when the corporate sponsor filed a patent application on the very same invention also including the university's test results, an interference was declared by the PTO since two applications on the same invention were pending.

In such a contest, it is not the earliest conception and reduction to practice dates that count; rather the question to be determined is whether the corporate sponsor disclosed the invention to the university fully and completely so that the university actually derived the knowledge from the corporation. In the derivation cases with which this author is familiar, it was the corporation that prevailed over the university. The lesson to be learned from these experiences is that whenever a corporation discloses inventive concepts or research

projects to universities to enable them to do certain desirable or necessary testing, all such disclosures and discussions should be clearly and fully documented.

Thus, conflicts of interest may "raise their ugly heads" when corporate sponsors undertake to prepare, file and prosecute patent applications based on sponsored-university research.

There is another, recently-highlighted problem or storm cloud, epitomized by the "infamous" *Singer* case (*Singer v. The Regents of the University of California, Calif. Court of Appeals, 1st district, 1997; No A076331)*, the court held that the university gave overly favorable licensing terms to companies in return for sponsored research funds, depriving the inventors of substantial potential royalties. Thus, in licensing negotiations, trading-off of benefits to the university may conflict with the expectations of the researchers. As regards the impact of *Singer*, Mark Bloom, Manager of Licensing & Sponsored Programs at The Cleveland Clinic Foundation, has this to say:

> It is premature to speculate on the impact that *Singer* will have on university technology transfer activities in states other than California. However, fears abound that the financial integrity of Universities will be jeopardized by their being subjected to inconsistent liabilities or, at the very least, that there will be a reduction in corporate-sponsored research. It is also likely that Universities will review and perhaps revise their patent and/or employment agreements and policies to address any future *Singer* situations. Furthermore, open communication between a University's TTO and other campus offices may be negatively affected. Finally a University TTO may consider becoming an independent entity like WARF, (Wisconsin Alumni Research Foundation) , i.e. a 501©(3) non-profit corporation, to more completely separate the patent and licensing function from the sponsored research function. (Mark G. Bloom, "University and Other Non-profit Organization Licensing: An Insider's Perspective," Ninth Annual Advanced Licensing Institute, Franklin Pierce Law Center, Concord, NH, July 17, 2000.)

F. Conclusion

As can be seen from the above overview, policies and practices regarding research contracts between universities and enterprises have reached a stage of great complexity and sophistication, even without the inclusion of the consequences on ownership and licensing/technology transfer of governmental funding and federal policy and legislation. However, in light of the vast experience inside universities and corporations in the area, the extensive literature (including model agreements) and the many programs dealing with the issues, and the objectivity, realism and professionalism exhibited by the "players and

actors" in this field, negotiation and preparation of license and research agreements between universities and corporations are greatly facilitated, albeit still challenging.

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