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of the Association of University Technology Managers™

Volume IV

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EDITOR'S PREFACE

With Volume IV of the AUTM Journal we continue our mission of presenting topics of interest to those involved with intellectual property, both inside and outside the university setting. The five papers included in this volume highlight issues that technology managers deal with on a regular basis: questions of ownership of inventions, product liability, special strategies for licensing plant and biological materials, and for negotiating with state universities.

In her paper entitled "Ownership of University Inventions," Jean Weidemier emphasizes the importance of having a signed invention assignment agreement with faculty members and other university employees. She offers eight scenarios in which inventions may occur and describes positions that universities have historically taken in defending their right of title. Ms. Weidemier cites case law as a basis for the conclusions in each situation, and provides a formal invention assignment agreement. The "moral" of the article is that "employees and visitors in a position to invent should be required to sign Invention Assignment Agreements as often as employees sign W-2 forms."

Robert Fissel's article illustrates the complexities involved in protecting and licensing new and useful plant material. He recommends policies and procedures for maintaining proprietary interest in plant material. Mr. Fissell describes the types of protection available and their respective shortcomings, and concludes with a list of questions to be answered when developing a license agreement, along with contractual terms to be considered.

In his article, "Theories Opposing the Imposition of Product Liability on (University) Patent Licensors," Gregory Hauth responds to the opinions expressed by Rosenblum and Fields in their paper, "Product Liability Risks of Licensing and How They Affect Commercialization of University Research," published in the 1991 AUTM Journal. Mr. Hauth disagrees with the theory that, as in trademark cases, breach of warranty and strict liability can extend liability to patent licensors. To support his position, he cites relevant case law, offers theories opposing strict liability, and analyzes the

courts' view of intellectual property as intangible property. Mr. Hauth also examines the Model Uniform Product Liability Act (MUPLA) and stresses the importance of a well-written license agreement.

Katherine Chapman and Patricia Ohlendorf have collaborated to write an informative article on technology transfer issues peculiar to state universities. They address the restraints imposed by state governments that licensees or licensors encounter when negotiating with a state institution. The authors include sample terms and conditions, with the hope that this proposed language may ease future negotiations among contracting parties. The final paper, adapted from a workshop given by Annie Yau-Young and Marilyn Ziemer at the 1992 *AUTM Annual Meeting*, offers a strategy for licensing in the special area of biotechnology. It indicates how the key terms and fee structure of the license can significantly influence both the way in which a technology is used and the financial return to the licensor. The authors take us through the terms and conditions of the biotechnology license agreement, specifically focusing on creative approaches for this challenging technological area.

I acknowledge with special thanks the assistance of Ms. Diane C. Hoffman, and welcome her to the position of Managing Editor. In the coming year the Journal will move to a two-volume format. In addition, we intend to add a "Letters to the Editor" section, in order to allow those with varying perspectives to express their views either on the published papers or on other matters concerning management of intellectual property.

We welcome original papers on topics of interest to professional technology managers and their colleagues in related fields. Those contemplating a potential article or a letter to the editor are encouraged to contact the Editor or Managing Editor regarding content and review procedures.

Jean A. Mahoney, Editor
November 1992

Ownership Of University Inventions

By B. Jean Weidemier

Summary:

Who owns an idea? A prototype? A patent? Assignment of inventions to an employer can seem illogical to the free- thinking university researcher. What can the university administrator do to minimize friction between the employer and the employee relative to patent ownership? When is the law black and white, when gray?

The starting point of the law is that individuals own their inventions, **except:** (l) where there is an express agreement providing for assignment of inventions to an employer; and (2) where an implied agreement to assign is found because the employee:

(a) was hired or assigned to invent; or,

(b) was hired or assigned to solve a specific problem; or,

(c) stood in a fiduciary capacity to the employer (President of a commercial company, for example).

Where no written agreement exists and no implied contract to assign is found, the inventor will own the invention, subject to the employer's shop- right to use the invention if the invention was made with the employer's resources or facilities.

But, how are these rules applied? Is a professor "hired to invent?" The following fact patterns provide a framework for analyzing the practical application of the above rules in the daily business of a university licensing office.

(l) Unreasonable Inventor (Signed Invention Assignment Agreement). The day Professor Z started work at the university he signed a clear and unambiguous Invention Assignment Agreement (see Appendix A for sample), along with his W- 2 form. He has had a three-year federal contract with a work statement to perform "research in the area of solar light bulbs." He invented a solar light bulb while working in his university laboratory between 9 a.m. and 5 p.m. on a Wednesday. He has refused to assign the invention to the university, because "after all, it was my idea."

There is no question that Professor Z must assign his invention to the university. In an action by an employer to compel assignment of an invention by an employee, pursuant to a written Invention Assignment Agreement, an employer must show: (l) the invention was conceived during the term of employment; (2) the assignment was governed by a valid, binding and enforceable contract; and, (3) all conditions in the assignment contract were met by the employer. *Mosser*

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Industries, Inc. v. Hagar, 200 U.S.P.Q. 608 (1978). In this example, all of these elements could be shown.

To diffuse the situation, the university could suggest that Professor Z contact the university's attorney or his own attorney. By seeking professional advice, Professor Z should become convinced that this issue does not merit his time. In addition, the University may want to emphasize to Professor Z any university policy of sharing royalty revenue with inventors personally from the licensing of university inventions.

(2) Unreasonable Inventor Who Slipped Through the Cracks (No Signed Invention Assignment Agreement). Professor Z invented his solar light bulb under the same circumstances as in Example (1) above; however, Josie from Personnel was out sick with the flu on Professor Z's first day of work and the temp thought he only had to sign the W- 2 form. Professor Z never signed an Invention Assignment Agreement.

Because of the federal funding, 37 C.F.R. [[section]] 401(14) applies regarding election of title by the contractor (the university) within two years of disclosure of the invention. 37 C.F.R [[section]] 401.14 (f) also requires the contractor to have written agreements with its employees (other than clerical and nontechnical employees) requiring (i) the disclosure of all subject inventions promptly and (ii) the execution of all papers necessary to file patent applications. Unfortunately, the university is in breach of its federal contract covering Professor Z's invention. Professor Z has hired an attorney, whose wages are being subsidized by Professor Z's potential licensee who has locked Z into a sweetheart deal. The university scrambles to locate a copy of the latest Patent Policy which was revised and mailed to all faculty members last year, and which states in part:

It is the policy of the university that individuals through their employment by university or by participating in a sponsored research project, or using university-administered funds or facilities, thereby accept the principles of ownership of technology as stated in this policy. In furthering such undertaking, all participants will sign Invention Assignment Agreements...

and,

Inventors/Authors will own inventions/materials which are:

(a) not developed in the course of or pursuant to a sponsored research or other agreement;

(b) not created as a "work- for- hire" by operation of copyright law and not created pursuant to a written agreement with university providing for a transfer of copyright or ownership to university; and,

(c) not developed with the significant use of funds or facilities administered by university.

The university's lawyer produced the often- cited case of *United States v. Dubilier Condenser Corp.,* 289 U.S. 178, 53 S.Ct. 554, 77 L.Ed. 1114 (1933) which states that:

One employed to make an invention, who succeeds, during his term of service, in accomplishing that task, is bound to assign to his employer any patent obtained. The reason is that he has only produced that which he was employed to invent. On the other hand, if the employment is general, albeit it covers a field of labor and effort in the performance of which the employee conceived the invention for which he obtained a patent, the contract is not so broadly construed as to require an assignment of the patent.

Another early case brought to the university's attention is *Solomons v. United States,* 137 U.S. 342, 346, 11 S.Ct. 88, 89, 34 L.Ed 667 (1890), which states:

If one is employed to devise or perfect an instrument, or a means for accomplishing a prescribed result, he cannot, after successfully accomplishing the work for which he was employed, plead title thereto as against his employer. That which he has been employed and paid to accomplish becomes, when accomplished, the property of his employer.

In this example, the key question to answer in determining the ownership of the invention becomes whether Professor Z was "hired to invent" a solar light bulb, or whether his employment was "general." Actually, on the fateful day he was hired ten years ago, no one had even remotely considered the idea of a solar light bulb. Professor Z was employed to teach several classes and to conduct research generally on solar power. His first seven years of research were devoted to solar- powered cars.

The "hired to invent" rule clearly envisions that specific job assignments can change during the course of employment and the question of fact turns on the circumstances and current job assignment at the time of invention. Therefore, the change in focus of Professor Z's research from solar cars to solar lightbulbs over the ten- year period is relevant. "An employee, who undertakes upon the direction of his employer to solve a specific problem within the scope of his general employment, is as truly employed and paid for the particular project as if it had been described at the outset in the contract of employment." *Houghton v. United States,* 23 F.2d 386, 390 (4th Cir. 1928).

In *Standard Parts Co. v. Peck,* 264 U.S. 52, 59 (1923), Peck was employed to solve a particular problem and a written contract required him "to devote his time to the development of a process and machinery for the production of the front spring now used on the product of the Ford Motor company" in return for $300 per month, plus several bonuses. The contract was silent on the matter of invention ownership, which became the subject of the law suit. The Court found the answer "inevitable and resistless": the "process and machinery" contracted to be developed for the company belonged to the company, not to Peck, who was otherwise paid for his services.

Whether the work statement in Professor Z's federal contract is specific enough to cover the development of a solar light bulb would be a question of fact, under a *Standard Parts* rationale. In *Patent Law Fundamentals*, Section 11.04, *Rights of Employer and Employee Inter Se,* the analysis goes one step farther; and it is stated at 11- 23, that "apparently" an employer would own inventions when an employee was "employed to plan and conduct fundamental and practical investigations and such lead directly to an invention," so long as the employee's area of activity was defined with "sufficient specificity."

In *Speck v. North Carolina Dairy Foundation, Inc. et. al.,* 311 N.C. 679, 319 S.E. 2d 139 (1984), the inventors were professors and researchers who developed a secret process; they had not signed Invention Assignment Agreements. They were paid by the university and acknowledged that the process was developed at the university using university resources. The Supreme Court of North Carolina found that, although there were no signed Invention Assignment Agreements, professors and researchers were hired to invent and their invention belonged to the university. "[t]hey developed the secret process...while employed as teachers and researchers to engage *inter alia* in just such research and development for the University." 1319 S.E. 2d 139 at 143.

An even more recent university case is *University Patents, Inc. v. Kligman et. al.,* 762 F. Supp. 1212 (1991). Dr. Kligman invented a Vitamin A preparation to slow the effects of aging of the skin. As with Professor Z, Dr. Kligman never signed an Invention Assignment Agreement; Dr. Kligman never signed an invention disclosure statement either. Some university resources were used, although Dr. Kligman was not as closely connected to the university as the inventors in the *Speck* case. Animal studies were conducted at the university by Dr. Kligman's wife, Lorraine, pursuant to a Johnson & Johnson contract, and a clinical study was performed at the university's Aging Skin Clinic.

University Patents, Inc. (with whom the University of Pennsylvania had contracted to exploit its patents) relied primarily on the university's patent policy set forth in the employee handbook to prove an implied contract to assign. Under the University of Pennsylvania's policy, all inventions resulting from work performed on university time or at university expense were owned by the university.

Pennsylvania law is not clear on the question of whether an employee handbook can create an employment contract. The Court applied traditional patent assignment principles to the more controversial handbook concepts. The University of Pennsylvania's handbook "clearly was not communicated as a definite offer of employment." (762 F.Supp 1212 at 1228). The opening comments in the handbook provided in part that, "we hope that this Handbook will serve as a *useful traveler's guide* (emphasis added)...," i.e., rather than a contractual legal document.

In April, 1991, the U.S. District Court for the Eastern District of Pennsylvania concluded that a "jury reasonably could find that an implied contract to assign the patent in question was formed between Dr. Kligman and the University [of Pennsylvania]." 762 F. Supp. 1212 at 1234. The university conveyed and enforced its Patent Policy in a rather lax manner over the years, but the court found "[t]here is evidence, however scant, from which one could find that Dr. Kligman was aware of the Patent Policy since August, 1967 and manifested an intent to be bound by it." 762 F. Supp. 1212 at 1234.

The issue of whether professors and university researchers as a class are "hired to invent" when pursuing their field of research was not addressed. The court cautioned that employers are advised not to rely on handbooks to govern the assignment of patent rights; certainly it is not difficult to deal with such issues explicitly in an express Invention Assignment Agreement.

A third case, *Regents of University of Colorado v. K.D.I. Precision Products, Inc.* 488 F.2d 261 (1973), although involving a different central issue, stated at Page 267 that "the subject of the University's employment was research directed towards the obtaining of patents." This supports the concept that university professors and researchers are employees "hired to invent."

But, back to Professor Z and our example. The law is not settled as to whether university professors and researchers are "hired to invent." What is the likely outcome for Professor Z? In the university's favor are the facts that:

- The failure to have Professor Z sign the Invention Assignment Agreement was a one- time error, not the result of a lax pattern.
- All professors were recently mailed a copy of the Patent Policy.
- Professor Z's invention fell squarely within the statement of work of his current federal contract, his assigned project.

And in Professor Z's favor:

- He never signed an Invention Assignment Agreement.
- It was his first invention, and he had never been through the procedure before. (See *Mainland Industries, Inc. v. Timberland Machine and Engineering Corp.,* 218 U.S.P.Q. 662, 665 (Ore. Ct. App. 1982)).

As a practical matter, a university should tighten its procedures for having all employees and visitors sign Invention Assignment Agreements on their date of arrival. Procedures can be added to double check the existence of such agreements for particular inventors before action is taken on new invention disclosures by the university licensing office. Research contracts, with the government and other sponsors, should have a checklist item on the existence of Invention Assignment Agreements for the principal investigator and other researchers.

(3) Conception at Home on Saturday Afternoon (Invention Conceived Outside of Employment). Professor Z invents the solar light bulb in his driveway on Saturday afternoon after a minor hit on the head incurred falling off his son's

skateboard. He refuses to assign the invention to the university because, "I invented it on my own time."

In this case, Professor Z properly signed the Invention Assignment Agreement on his first day of work. Ownership in this example would depend on the exact wording of the Invention Assignment Agreement. As a matter of policy, each university must decide what is fair, what is too far-reaching. Probably a university would be most prudent to require inventors to assign this Example (3) type of invention to the university. Otherwise, sponsors would be shortchanged by the conception of the invention in the driveway, despite the years of government-funded background research at the university.

In *Mainland Industries,* the inventor was a salaried employee who did not work specific hours and never signed an Invention Assignment Agreement. He was uncertain whether the patentable idea was conceived at home or at the office. The court stated at 665, "the place where an invention is developed is not determinative of whether the employer or the employee is entitled to a patent."

As a practical matter, most likely Professor Z will return to work at the university on Monday morning, will revamp his work schedule and list of priorities toward the goal of making Saturday's idea into a working prototype, and will assign three graduate students to go full speed ahead reducing the idea to practice. Professor Z is now clearly using university-administered funds and facilities to develop the invention, and the university would own the patent rights, under the hypothetical Invention Assignment Agreement in Appendix A and the Patent Policy in Example (2).

(4) Eclectic Inventor (Invention Outside Assigned Area of Research). Professor Z, instead of inventing a solar light bulb, develops a remarkable new fertilizer for tulip bulbs, borrowing his colleague's lab in the Botany Department and two research assistants on Tuesday afternoons as a diversion from his solar projects. A frantic search of the records is futile; Professor Z never signed the Invention Assignment Agreement.

The *Dubilier* case referenced in Example (2) above presented a similar set of facts. Francis Dunmore and Percival Lowell were employed by the government in the radio section of the Bureau of Standards and performed research and testing in the laboratory. In the fall of 1921, Dunmore and Lowell were considering the problem of applying alternating current to broadcast receiving sets. This project was unrelated to the work of the radio section and not assigned to them by any superior. They took it on independently and voluntarily.

Dunmore and Lowell discovered a remote- control system for airplane bombs and torpedoes and were permitted to pursue their work in the laboratory and perfect the prototypes after disclosing their discovery to their section chief. Dunmore and Lowell did not sign Invention Assignment Agreements, and no one advised them that they would be expected to assign their rights to Uncle Sam. Dunmore and Lowell instead assigned to the Dubilier Condenser Corporation.

The Supreme Court held that the work was not part of the work specifically assigned to them, and therefore, the employees had title. The government was granted the royalty- free right to practice the inventions, which is known as a shop- right. Shop- rights are granted where "a servant *[employee would now be more politically correct]* during his hours of employment, working with his master's materials and appliances, conceives and perfects an invention for which he obtains a patent, he must accord his master a nonexclusive right to practice the invention." 289 U.S. 178, 188.

Dubilier also settled the question of whether the character of the service calls for different rules as to the relative rights of the government and its employees. The answer was no, the same principles of employer-employee apply.

In the example, this is all good news for Professor Z. He would probably own his tulip bulb invention; the university would have a royalty- free, nonassignable right to practice it.

Again, all controversy could have been resolved if Josie in Personnel had been able to handle Professor Z's paperwork herself. If Professor Z had duly executed the hypothetical Invention Assignment Agreement, the tulip bulb invention would have been owned by the university, because the significant use of university-administered funds and facilities was encompassed by the Agreement.

(5) Precocious Undergrad (Student Inventor: No Invention Assignment Agreement). Professor Z is filled with joy. After years of lecturing to a sea of bored, young faces, Jennifer, then a sophomore, appears in his Advanced Solar class. While chatting after class about Professor Z's long struggle to harness the sun's power in a 60- watt light bulb, Jennifer asks the key question, "Why not do it this way...?" She performs a simple experiment demonstrating that her idea will work. Professor Z puts his lab at her disposal, and Jennifer spends every free moment for the next year in the lab developing a prototype.

Undergraduates at the university are not routinely requested to sign Intellectual Property Agreements unless employed as Research Assistants. Jennifer is wildly rich, so she saw no need to work while at school and never signed the Agreement. Students were not issued copies of the Patent Policy, and frankly, she did not even consider the patent ownership issue in her passion for the work.

A problem arose after graduation when Professor Z filed an invention disclosure with the university licensing office naming himself and Jennifer as co- inventors and citing the federal research support. Jennifer refused to assign to the university and denied that Professor Z was a co- inventor. "He was *in the way,"* she recalled. Professor Z ultimately conceded this issue after the university's patent counsel defined "inventorship" for him, and all agreed that Jennifer was sole inventor.

In this case, as in the *University Patents* case above, there is no signed Invention Assignment Agreement, and the university is relying solely on its Patent Policy.

Under the hypothetical Policy described in Example (2), the university would own Jennifer's invention because of her use of significant funds and facilities, regardless of the lack of a signed Invention Assignment Agreement.

In a court battle, with Jennifer's formidable resources and top New York attorneys, the university would have an uphill battle to prevail. Jennifer probably could not be imputed reasonably with knowledge of the terms of the Patent Policy and its applicability to her. The university might be left with just a shop-right.

Again, if she had signed the Invention Assignment Agreement, the result would be different: most likely the university would own the invention because of her significant use of funds and facilities. Whether or not a university routinely should have undergraduates sign Invention Assignment Agreements would be a matter of thoughtful policy making for each university.

(6) The Better- Late- Than- Never Agreement (Invention Assignment Agreement Signed After Years of Employment). Professor Z did not sign the Invention Assignment Agreement on his first day of work. He invented the solar light bulb five years later, and coincidentally two weeks after his discovery he received an Invention Assignment Agreement form as part of a university licensing office cleanup project and signed it.

The courts are divided on whether continuation of employment is adequate consideration for such an Agreement when it is signed after the employer-employee relationship has been formed. (See *Mirafi, Inc. v. Murphy,* 14 U.S.P.Q. 2d 1337, 1350 (W.D.N.C. 1989) any agreement after the employer/employee relationship has been formed must have new consideration to be enforceable; and *Harsco Corp. v. Zlotnicki,* 779 F.2d 906, 228 U.S.P.Q. 439 (3rd Cir. 1985) agreement held to cover assignment of invention to employer although not executed by employee until after he made invention, as agreement used past and present tenses and referred to entire term of employment).

In *General Signal Corp. v. Primary Flow Signal, Inc. et. al.,* C.A. Nos. 85- 0471B, 86- 034B (DC RI 1987), Dezsoe Halmi was employed by General Signal (GSC), rising from the position of draftsman to Products Development Manager. Mr. Halmi was employed for 15 years before he was asked to sign an "Employee Confidential Information and Invention Agreement," which he signed. The Agreement required him to assign to GSC his inventions made while working at GSC and for six months thereafter.

On April 5, 1983, five days after the six- month period ended, Mr. Halmi recorded the conception of a universal flow meter that was later patented and manufactured and sold by Primary Flow Signal, Inc., a company which Mr. Halmi established after leaving GSC.

The court found that his continuing employment was adequate consideration for the Invention Agreement. The court also found that, "The perfection of a flow

meter proved to be a painstakingly intricate process involving extensive testing. It is therefore difficult to believe that after a long and distinguished career with Plaintiff, Mr. Halmi in his musing five days after the trailer clause expired for the first time came up with the idea for the NTV. Although the word 'Eureka!' has allegedly been uttered by more than one inventor over the years, the concept at issue does not lend itself to such sudden discovery."

The court concluded the idea must have occurred to Mr. Halmi while employed at GSC, and therefore, Mr. Halmi was in violation of the Invention Agreement.

The university can take some steps to protect itself from situations where the Invention Assignment Agreement is not signed on the first day of employment and for inventions not reported by employees who leave the university. As mentioned in Example (2), various catch mechanisms can be put in place to ensure that Invention Assignment Agreements are on file. If it is discovered that an employee has not signed an Agreement, a carefully-worded Agreement signed later provides some assistance in many jurisdictions. The Agreement should state that the consideration is the continuation of employment and the continued use of university funds and facilities and that the entire term of employment is covered. Some additional consideration could be given, for example, the payment of the sum of $10.00. Any royalty- sharing right under the university's Patent Policy should also be cited.

On termination of employment, personnel should be asked to sign an exit form to the effect that "I have disclosed all my inventions falling within the terms of the Invention Assignment Agreement to the university licensing office."

(7) The Visiting Scientist. Professor Z corresponds regularly with his college chum Marge Xcaliber who is a tenured professor at another university halfway across the country. One hot summer Professor Z is feeling stultified in his work and invites Professor Xcaliber to spend some time collaborating in his air-conditioned solar lab. She is compensated through funds from Professor Z's federal contract. The collaboration succeeds, and Professor Xcaliber breaks through the impasse Professor Z had been struggling with for almost a year. She reduces her idea to practice that summer, and the invention is clearly novel and patentable. But she did not sign the visiting scientist Invention Assignment Agreement from Professor Z's university. Her university is claiming ownership and produces a valid, unambiguous Invention Assignment Agreement, which covers all inventions made during her period of employment, regardless of where conceived or reduced to practice.

Again, the university is in a bit of trouble under its federal contract because this researcher did not sign an Invention Assignment Agreement. Again, the university is left relying on a Patent Policy that states the university owns inventions made by visiting scientists making significant use of funds or facilities. Professor Xcaliber may never have seen the Patent Policy document.

The university could argue that Professor Xcaliber should have known that Professor Z's university would have some sort of patent policy and made reasonable inquiry. No case law came to light on this situation, but most likely Professor Xcaliber's university would own the invention with Professor Z's university getting a shop right. This might be a good case to negotiate for joint ownership by the universities. Another possibility for compromise is to recognize the contribution of both universities by a patent cost and license royalty-sharing arrangement. Aside from the equities on both sides, as a practical matter Professor Xcaliber's university may find itself on the other side of a similar situation in the future and may want to generate goodwill.

(8) Inventor Who Doesn't Play Well With Others (Inventor Refuses to Sign Invention Assignment Agreement). Professor Z did not sign the Invention Assignment Agreement on his first day of work, but was requested to sign five years later during the licensing office's cleanup project. He refused, saying, "My ideas and thoughts are not for sale." The department head and administration do not want to interfere, fearing Professor Z will be further upset and instead ask the licensing office to do the best they can.

Without upper level pressure relating to Professor Z's job security, the licensing office can only argue that:

- the Patent Policy applies in any event, and Professor Z should sign the Invention Assignment Agreement merely to affirm;
- licensing of inventions will be blocked by the potential for future ownership disputes between Professor Z and university; and,
- the university will take legal steps to pursue its ownership rights to inventions made by Professor Z falling within the Patent Policy.

Conclusion

Under the hypothetical Patent Policy in Example (2), an employee of a university is required to assign to the university all inventions made with university-administered funds and facilities if the employee signed a clear and unambiguous Invention Assignment Agreement. Even if no written contract exists, the university may own the invention. It is a question of fact to be decided in view of all the circumstances, and the contract may be implied from the relation of the parties.

The principles have evolved from the line of court cases in this area that, in the absence of a written agreement, the invention belongs to the employee inventor unless the employee was hired to invent or assigned to solve a particular problem. *Standard Parts Co. v. Peck,* 264 U.S. 52 (1923). In those cases, an implied contract to assign is found because the employee has only accomplished what he was hired to do. The employer also owns the invention if the inventor owes a fiduciary duty to the company (not discussed above, but see *Great Lakes Press Corp. v. Froom,* 695 F. Supp. 1440 [W.D.N.Y. 1987] where the relationship of President to company was one of special trust).

Again, where there is no written contract and no implied contract to assign is found, the inventor will own the invention, subject to the employer's shop- right to use the invention if the invention was made with the employer's resources or facilities.

There is one commentator who concludes that "[t]he common expectations concerning university employment are not the same as the expectations concerning employees within private industry." *"The Souring of Sweet Acidophilus Milk: Speck v. North Carolina Dairy Foundation and the Rights of University Faculty to their Inventive Ideas."* North Carolina Law Review, 63 Vol. 1248 at 1259, 1985 (discussed in Example (2) above). The author opines that the *Speck* court's "classification of university faculty as persons hired to invent is contrary to the premises upon which higher education is based." 63 Vol. 1248, at 1248. The argument is that professors are encouraged only to pursue knowledge through research.

This conclusion is unsupported by the case law, which does not distinguish between university and commercial employees; and, in fact, the recent cases of *Speck* and *K.D.I. Precision Products Inc.* found specifically that university professors and researchers are by definition hired to invent. The Supreme Court stated that government employees are governed by the same rules as private industry employees in *Dubilier.* The logical extension of *Dubilier* is to treat university employees, the bulk of whom perform research under government funding, equivalent to government researchers, and therefore, to be the same as commercial employees.

In *Houghton,* the employee- inventor, like the above commentator, argued that the "hired to invent" rule should not be applied where an employer, such as the government, does not seek a monopoly, which is the essence of a patent. The Court responded vehemently that "It is unthinkable that, where a valuable instrument in the war against disease is developed by a public agency through the use of public funds, the public servants employed in its production should be allowed to monopolize it for private gain and levy a tribute upon the public which has paid for its production, upon merely granting a nonexclusive license for its use to the governmental department in which they are employed."

Without a written agreement, the facts of each case would determine ownership; a particular professor may or may not be found to have been hired to invent or to resolve a particular problem. As with any class of employees, probably no blanket statement can be made as to university professors and researchers being hired to invent.

Moral

Employees and visitors in a position to invent should be required to sign Invention Assignment Agreements as often as employees sign W- 2 forms.

APPENDIX A

Invention Assignment Agreement

Name (please print or type):

Social Security No.

In consideration of the sum of One Dollar ($1.00) and:

* my past, present, and/or future employment at the Massachusetts Institute of Technology ("M.I.T."); and/or

* my past, present, and/or future participation in research at M.I.T.; and/or

* opportunities which have been made or to be made available to me to make significant use of M.I.T.- - administered funds or facilities; and/or

* opportunities to share in royalties and other inventors/author rights outlined in the "Guide to the Ownership, Distribution and Commercial Development of M.I.T. Technology" dated May 24, 1989, as that document may be amended from time to time (the "Technology Policy Guide"), I:

A. agree to disclose promptly to M.I.T. and hereby assign all rights to all inventions, copyrightable materials, computer software, semiconductor maskworks, tangible research property and trademarks ("Intellectual Property") conceived, invented, authored, or reduced to practice by me, either solely or jointly with others which:

(i) are developed in the course of or pursuant to a sponsored research or other agreement in which I am a participant as defined in Paragraph 2.1.1 of the Technology Policy Guide; or

(ii) result from the significant use of M.I.T.- - administered funds or facilities as "significant use" is defined in Paragraph 2.1.2 in the Technology Policy Guide; or

(iii) result from a work- for- hire funded by M.I.T. as defined in Paragraph 2.1.3 of the Technology Policy Guide; and

B. agree to execute all necessary papers and otherwise provide proper assistance, at M.I.T.'s expense, during and subsequent to the period of my M.I.T. affiliation, to enable M.I.T. to obtain, maintain or enforce for itself or its nominees, patents, copyrights or other legal protection for such Intellectual Property; and

C. agree to make and maintain for M.I.T. adequate and current written records of all such M.I.T. Intellectual Property; and

D. agree to deliver promptly to M.I.T. when I leave M.I.T. for whatever reason, and at any other time as M.I.T. may request, copies of all written records referred to in Paragraph C. above as well as all related memoranda, notes, records,

schedules, plans or other documents, made by, compiled by, delivered to, or manufactured, used, developed or investigated by M.I.T., which will at all times be the property of M.I.T.; and

E. not to disclose to M.I.T. or use in my work at M.I.T. (unless otherwise agreed in writing with M.I.T.):

(i) any proprietary information of any of my prior employers or of any third party, such information to include, without limitation, any trade secrets or confidential information with respect to the business, work or investigations of such prior employer or other third party; or

(ii) any ideas, writings, or Intellectual Property of my own which are not included in Paragraph A. above within the scope of this Agreement (please note that inventions previously conceived, even though a patent application has been filed or a patent issued, are subject to this Agreement if they are actually first reduced to practice under the circumstances included in Paragraph A. above).

After the date hereof, this Agreement supersedes all previous agreements relating in whole or in part to the same or similar matters which I may have entered into with M.I.T.

It may not be modified or terminated, in whole or in part, except in writing signed by an authorized representative of M.I.T. Discharge of my undertakings in this Agreement will be an obligation of my executors, administrators, heirs or other legal representatives or assignees.

I represent that, except as identified on the reverse side hereof, I have no agreements with or obligations to others in conflict with the foregoing.

Witness Signature (To include first name in full)

Date

Note: A detailed discussion of M.I.T.'s policy related to intellectual property is outlined in the "Guide To the Ownership, Distribution and Commercial Development of M.I.T. Technology" referenced above. This document is available upon request from the Technology Licensing Office.

(To be made out and signed in triplicate. Distribution: original copy to the employee's personnel file; second copy to the employee; and third copy to the Technology Licensing Office.)

Protecting and Licensing Plants Developed Through University Research

Robert E. Fissell

University Plant Breeding Research Environment

Plant breeding at a university occurs to further the science, to teach the science to others, and/or to develop new and useful plant cultivars for specific purposes.

Traditional plant breeding takes time and money. Because of the length of time and the nature of field trials, traditional breeding is not always on the cutting edge of science and does not always assure quick advancement and recognition within the present academic environment. However, the majority of cultivars now in use within the United States (US) and other countries were developed and still are being developed using traditional methods. With federal and state research budgets for universities declining, administrators are hesitant to fund expensive, long-term breeding programs not financed from other sources. Biotechnology research occurring in university and private labs has successfully inserted or recombined new genetic material into certain types of plants, each such insertion or recombination resulting in a new plant selection, some useful, some not. Biotechnology is on the cutting edge of science and attracts significant research dollars and research papers on plant biotechnology flood academic journals, but both traditional plant breeding and biotechnology should contribute greatly to future progress in improving agricultural crops.

Plant material and/or germplasm is secured by the plant breeder either locally or globally. The breeder may screen the plant material collected and/or recombine the collected germplasm many times over to annually screen hundreds or even thousands of individual selections. Advanced selections undergo extensive field trials.

The breeding work at universities may be funded by for-profit industry (both domestic & foreign), by non- profits, by the federal or state government or by various combinations of funding from these or other sources. University scientists cooperate with colleagues in private industry, either as consultants using private funds and facilities or as principal investigators under cooperative research agreements using university funds and/or facilities. They also exchange germplasm with breeders from other countries, and private industry provides novel and useful genetic material to university colleagues, or vice versa.

University scientists sometimes desire to test their new plant selections in various micro- climates and soil conditions at non- university owned or controlled sites. To reduce research expenses, they will often use private nurseries or seed companies to propagate advanced selections for test plantings.

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How does a university technology manager, charged with protecting and licensing new and useful university plant material, operate successfully in this environment?

Maintaining a Proprietary Interest in Plant Material Prior to Legal Protection and Licensing

Because of statutory bars inherent in all laws dealing with the legal protection of plant material, it is essential for a university to maintain a reasonable degree of control and a proprietary interest in its novel plant material prior to applying for US or foreign protection. Policies must be flexible enough not to hamper the testing of material or the exchange of material between breeders, yet formal enough to preserve both property rights in the material and the right to obtain patents or variety protection.

Policies regarding protection and release of plant materials should be an integral part of handbooks for faculty whose research is likely to involve creation of novel plant selections. Disclosure should occur at the time the commercial usefulness of a given plant selection is determined. If testing plant selections on non-university land is to occur, the test grower and the university should execute a written test agreement before the research takes place. It is best to avoid informal oral understandings between researchers and non- university third parties. Test agreements should maintain ownership of the material in the university, prohibit further propagation or transfer of material without written authorization, and limit the number of plants that can be under control of the test licensee at any one time. Should private nurseries assist a breeder in propagating material for testing, the nursery also should be under written agreement specifying that material may only be transferred with written authorization of the breeder to growers who have previously executed test agreements. Off- university site testing should only be for bona fide research purposes. It is also preferable to have on- site test locations fenced and marked with "no- trespassing" signs whenever possible. When showcasing advanced selections to the general public, it is advisable to have sign-up sheets for visitors and advise them that the plant material they are viewing is proprietary to the university.

Publications merely describing the characteristics of a new plant selection are not considered enabling and thus are not a bar to obtaining US protection because readers cannot reproduce the cultivar without having access to the plant material. On the other hand, if a publication describes with certainty both the characteristics of a new selection and the selection's location on publicly accessible land, this could act as a bar to obtaining US protection, provided the filing date was not obtained within one year from the date of publication.

Publications enabling others skilled in the art to duplicate biotechnology inventions are a bar to obtaining US protection if the publication occurs one year prior to obtaining a US filing date. Further, the publication is an immediate bar to obtaining protection under the patent laws of most foreign countries.

The University should implement and circulate policies and procedures addressing similar concerns to faculty working in plant biotechnology. Faculty members should use secrecy agreements for exchange of proprietary information and "biological materials transfer agreements" in place of test agreements for the exchange of cellular or tissue culture materials.

Types of Protection

Each new plant selection created by traditional breeding methods or recombinant DNA techniques may be novel in some respect and thus eligible for protection under US plant patent (US PLP) or plant variety protection (US PVP) laws. Even plants collected directly from an uncultivated site, if screened and reproduced under cultivation and found to exhibit and maintain some unexpected and useful trait, may be protected.

Since the US Supreme Court's Chakrabarty decision of the early eighties, it is now possible, in theory, to patent (under Section 101 of US patent law) anything under the sun that is made by man, including living organisms, provided: l) the living starting material; 2) the living end- result creation; and/or, 3) the process leading to the living end- result creation is novel, useful, non- obvious and meets certain other statutory requirements.

Many patent attorneys now maintain that any novel and useful plant selection can be protected under Section 101 of the patent laws, whether the selection was developed using traditional breeding methods or using biotechnology. Section 101 patents are allowed multiple claims, and thus can protect not only the reproducible plant and seed, but other parts of the plant as well. For this reason, a Section 101 patent can afford substantially more protection than a plant patent or plant variety protection certificate, and can provide a basis for collecting royalties on annual fruit sales, for example, rather than only on a "one- time" sale of plant material. However, Section 101 patents are more expensive, difficult, and time- consuming to obtain than are US PLP or US PVP certificates. Section 101 patents also require deposits of materials at a repository accessible to the public.

Foreign laws protecting certain plant species are available in countries belonging to the Union for the Protection of New Plant Varieties (UPOV), an international treaty administered in Switzerland and acceded to by the United States in November, 1981. As there is not a mechanism for one international filing through UPOV for protection in multiple countries, separate applications must be filed in individual member countries. A plant type for which protection is desired may not be on the "National List" of plant types that can be protected in a given country. Plant material must be submitted for examination, and protection will not issue until the examination is finished. The applicant must complete a technical questionnaire for the application. The format used and information requested in these questionnaires may vary widely from country to country for the same plant type. Also, laws governing protection vary from country to country, and plant quarantine or other agricultural laws and regulations may affect an applicant's plan to commercialize certain protected plant types in any given country.

UPOV regulations prohibit the use of trademarks for generic cultivar names used in applications for protection under UPOV, but an applicant's choosing both a name to use in the application and a separate, trademarked "fancy name" to market plant material is a common practice in the nursery trade, both in the US and in other countries.

Shortcomings of US Plant Protection Laws

US Plant Patent Laws: Unlike the US PVP laws, which expressly give the owner of protection the right to prohibit the export and import of protected seed from and into the US, US PLP laws are silent concerning export and import of the plant material they protect. An express granting of the right to similarly prohibit the export and import of plant material protected under US PLP laws would be a great improvement. Further, if plant parts (e.g., fruits, nuts) are readily distinguishable from others of their kind, US PLP law might also be amended to grant the patent owner the right to prohibit the unauthorized export and import of such plant parts from and into the US. US PLP laws are an anomaly, in that they require no deposit of plant material in a publicly accessible repository. Thus a US PLP is not truly enabling. A US PLP owner may maintain an exclusive property interest in a protected cultivar both during and after the term of protection. Others practicing the art of plant breeding may never benefit from the government's granting protection under US PLP laws.

US Plant Variety Protection Laws: US PVP laws give farmers producing seed of protected cultivars for other than reproductive purposes the right to sell the seed produced (from the protected seed) to another farmer for planting, provided the second farmer is also producing seed for other than reproductive purposes. Owners of US PVP would be better served if any reproduction of protected seed for the purpose of commercial sale or transfer to another party for replanting was an infringement of the certificate owner's rights. A US PVP owner would also benefit if other applicant- plant selections, having utilized a US PVP owner's protected cultivar in their development, were not afforded protection unless the utility of the applicant selections offered some improvement over the US PVP owner's earlier-protected cultivar.

Licensing Rights to Plant Materials

Licensing plant materials developed at a public university is not an easy task. In evaluating a potential plant selection and formulating possible licensing arrangements, the following questions should be answered:

l) Does the selection have a certain reputation from earlier test trials, or is it relatively unknown to industry?

2) Will the selection compete against similar cultivars, or will it offer unique advantages, possibly economic advantages?

3) Are there established industry royalty standards for cultivars of the selection's plant type, and, if so, are existing rates based on an exclusive or non- exclusive licensing arrangement?

4) Will the selection have potential in other states of the US or in other countries?

5) Is it industry practice for growers to buy plant material from the nursery or seed company sector, or is it likely that growers may increase material themselves?

6) What is the recent economic health of the industry using the cultivar?

7) What is the per-acre planting rate and what is the established commercial royalty rate applied per acre?

8) What is the royalty rate as a percentage of the present selling price of the plant material, and is it customary to give price discounts on large orders or on some other basis?

9) How much plant material is available for release to licensees, and will the distribution of available material need to be made on an equitable basis?

10) Are there plant health considerations concerning the plant material available for release to licensees?

When the majority of these questions are answered, a technology licensing manager may begin to put together the agreement(s) that will define the licensing program.

Contract exclusivity: Generally, US plant licensing by public universities is non-exclusive. However, at times there may be good reason to license plant selections on an exclusive basis. Some of those reasons are as follows: l) when the exclusive licensee is truly a neutral party who agrees to sublicense qualified nurseries or seed companies to propagate and sell on a non- exclusive basis and who agrees to monitor the enforcement of patent or certificate rights against infringement (if there is sufficient income stream from royalties to be shared with an exclusive, neutral third party licensee, this may reduce the costs for the university's administering a large-scale licensing program); 2) when the plant selection needs extensive, additional developmental work and further field testing before entering commerce; and, 3) when the selection has an extremely limited market or will compete against close, substitute selections and will need extensive promotion to be successful. In certain circumstances it may be a good idea to license propagation rights in the US exclusively by territory, but license rights to sell plant material on a non- exclusive basis throughout the US.

By contrast, foreign plant licensing is almost always on an exclusive basis wherein the university licenses rights under its protection, by territory, exclusively to a third party who monitors the enforcement of sub- contracts and infringement in the territory and collects and pays royalties to the university.

The goal of non- exclusive licensing in the US should be to set up a level playing field for licensees, and let them compete on quality and price of the plant material to be sold. If licensees or their customers from different states compete in the same markets, it is generally essential not to have differential royalty rates for plant material sold by licensees in the various states. An exception to this would be lower royalties in the home state if it can be demonstrated that the industry in the home state has contributed significantly to the research program leading to the development of the plant selection.

Royalty rate(s): Royalty rates in plant material licenses are generally set on either a "per unit sold" or "percentage of net sales price" basis. Percentage royalties can be a hedge against inflation, but set per- unit royalties remove the university's anticipated income from pricing decisions of the licensee and are especially advantageous if sales to end- users commonly go through other third parties. While collecting royalties on plant sales generally is the best method for a public university to follow in the US, in foreign countries, more restrictive licensing arrangements may enable the collection of royalties on fruit sales. A low initial royalty rate that is raised automatically after a certain number of years can act as an incentive for growers to experiment with a new cultivar whose performance in the field is not well established.

Miscellaneous: To protect foreign rights, it is essential to restrict exports of plant material of protected selections from the US. The US licensee should expressly agree in the license not to export or to assist in the export of plant material of the protected selection. Further, the licenses should require all purchasers to sign grower or distribution agreements in which the purchaser's right to use or resell the plant material is predicated upon an agreement not to export or assist in the export of plant material from the US. Grower and distribution agreements are useful tools for the owner of plant protection, as these documents specify what is expected of purchasers who use or re- sell protected plant material and, by signature of the purchaser, actively indicate the intent of the purchaser to comply with those expectations.

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Overview of University of California (UC) Agricultural Research, and California Agriculture

The University of California (UC) is a Land Grant institution, chartered in 1868. Its Agricultural Experiment Station, located on the Berkeley, Davis and Riverside campuses as well as at other research sites around the state has an annual research budget of around $140 million, 70 percent of which comes from the state of California. The Experiment Station provides research support to the agricultural sector, an industry having a 1990 farmgate product value of $17.8 billion. With approximately 85,000 farms on 3 percent of the productive farmland in the United States, California farmgate value comprises about 11 percent of the US total. Because of its coastal mediterranean climate and other inland microclimates, California agriculture is perhaps the most diverse of any region in

the world. Of its 20 leading agricultural commodities, only the leading commodity (dairy) makes up over 10 percent of the farmgate value. Ten of the top twenty crops individually account for less than 3 percent of the state's total gross farm income. Strawberries are a $400 million per year industry.

Plant Licensing Program at UC

UC has been protecting and licensing certain of its proprietary plant material for 20 years. The effort has been profitable, largely due in the early years to UC-developed winegrape cultivars and, more recently, UC-developed strawberry cultivars. Plant income last year was $2 million, 75 percent from strawberries. Since 1980, total plant income was $15 million. A full range of asexually propagated agricultural plant types (asparagus, avocados, citrus, peaches, winegrapes, tablegrapes, rootstocks, zoysia grass, woody ornamentals, etc.) are licensed, and, within the last year, a seed propagated artichoke cultivar was licensed to industry. Rights are licensed outside of California in other states and also in Australia, Chile, France, Italy, The Netherlands, New Zealand and Spain. UC's plant licensing group consists of 3 professional and 2 support staff who administer 75 US plant patents, 1 US plant variety protection certificate, 225 foreign applications or issued foreign protection certificates, and 377 license agreements.

Theories Opposing the Imposition of Product Liability on (University) Patent Licensors

Gregory W. J. Hauth

ABSTRACT

This paper proposes that courts have recognized an ongoing tension between the need for consumer protection, as established by product liability laws, and the need to encourage the disclosure of ideas and expressions by granting exclusive rights through patents and copyrights. A review of several cases and a model statute enacted by many states indicates that, contrary to advice circulated by some groups, most university patent licensors probably do not expose their institutions to product liability concerns that manufacturers of tangible products and trademark licensors must face if defective products are introduced into the stream of commerce. Introduction

This paper proposes that courts have recognized an ongoing tension between the need for consumer protection, as established by product liability laws, and the need to encourage the disclosure of ideas and expressions by granting exclusive rights through patents and copyrights. In considering product liability for intellectual property, only in certain trademark cases have courts built a legal "bridge" from the licensee to the trademark licensor, thereby imposing responsibility on the licensor under product liability theories. But courts that have considered applying product liability to "mere" owners or licensors of patents or copyrights have refused to erect such bridges, stating that extending product liability to patent and copyright licensors will extract a toll in the form of a chilling effect too great for society to bear. A review of several cases and a model statute enacted by many states indicates that, contrary to advice circulated by some groups, most university patent licensors probably do not expose their institutions to product liability concerns that manufacturers of tangible products and trademark licensors must face if defective products are introduced into the stream of commerce.

The Problem

Since the passage of the Bayh- Dole Act,[1] technology transfer has become an increasingly important and successful mission for universities. For the most part, universities rely on their ability to obtain patent or copyright protection for new inventions or works of authorship produced by their faculty and staff. University technology transfer offices convey the legal rights obtained from patents and copyrights through license agreements to corporations interested in bringing the inventions or new works to the marketplace. While the transfer of technology by universities has many positive aspects, questions persist regarding product liability risks associated with licensing university-owned technology to corporations.

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Assumption: Product Liability Extends to Patent and Copyright Licensors

Although many universities operate successful and growing technology transfer offices, these same universities as patent and copyright licensors worry that a corporate licensee may produce a faulty product based upon a licensed patent or copyright. Several sources may account for such concern. First, courts have determined that status as a licensor alone (such as a lessor or franchisor) does not protect a defendant from product liability. In *Cintrone v. Hertz Truck Leasing & Rental Serv.,* 45 N.J. 434, 212 A.2d 769 (1965), the long- term lessor of trucks was held strictly liable for an injurious defect that arose during the term of the lease. In another case, *Price v. Shell Oil Co.,* 85 Cal. Rptr. 178, 466 P.2d 722 (1970), the court said that "both lessors and sellers" are an integral part of the overall marketing enterprise that should bear the cost of injuries resulting from defective products." Attorneys and legal groups fuel the fire of concern, recommending that universities take an extremely precautionary approach such as that recommended by one legal group: "When a university *in any way* becomes involved in commercialization, even if only through the licensing of its discoveries, there is a risk that a product derived from the discovery will cause harm, and the institutions will be required to accept responsibility for at least a portion of that harm. Since the magnitude of that risk may be sufficient to bankrupt even the most financially stable institution, it is essential that great care be taken in embarking upon such activities."[2] The author, however, offers no evidence that such a risk actually exists, nor does he provide any evidence that the magnitude of such risk could bankrupt an institution. In another paper, Rosenblum and Fields add to the seriousness of this concern. They propose that cases that extend liability to trademark licensors may be used, through analogous reasoning, to extend product liability to patent licensors. Believing that a legislative solution is therefore needed to protect universities, Rosenblum et. al. state: "It seems inevitable, in the years ahead, that legislators as well as technology managers must come to grips with the paralyzing effects of product liability exposure."[3] This view -- that trademark cases that used theories of breach of warranty and strict liability can be used to extend liability to patent licensors -- also appears in earlier writings.[4] In the absence of knowledge to the contrary, many university and research institution licensors of patents and copyrights assume that product liability law indeed exposes them to liability. However, this assumption is unproven, as there are no examples of successful product liability lawsuits against universities. Certainly, no university wants to be the first such defendant successfully sued under product liability law for licensing its patent rights or copyrights. The question remains, however, whether a plaintiff could win a judgment against a university patent licensor under existing product liability law.

Existing Theories Opposing Strict Liability and the Chilling Effect

In an excellent article on this subject, Philip Goldman discusses four theories opposing imposition of strict liability on patent licensors.[5] He first argues that,

while one justification for imposing strict liability on a manufacturer is the difficulty of determining negligence, such justification does not apply in a license agreement when the license is clear, and where a plaintiff would not have an undue burden showing the extent of compliance with its terms. Secondly, Goldman discusses justification for imposing strict liability based on the economic ability of the parties (including the licensor) to bear and redistribute it. However, he argues that a licensee that created the injuring product, as well as the demand for the product, both controls and profits from it. Thus, the fact that the licensor may have accumulated resources in unrelated or even related activities does not justify transferring culpability to the licensor. In a third theory, he notes that one justification for strict liability is to deter manufacturers from making faulty products. The licensee, not the licensor, is best able to determine the safety and suitability of a given product for a given application. The licensee "balances the risks with the expected benefits and it is that balance which deterrence could be expected to affect."[6]

Goldman's fourth theory centers on policy implications of imposing strict liability. While he notes many useful purposes of patent licenses, an additional purpose from a research institution's view, and even from the nation's view, pertains to the ability of U.S. universities, research institutions, and federal laboratories to use patent licenses to transfer developments produced from billions of dollars worth of research funding. "[T]o complicate the relatively well- settled and socially valuable behavior of innovation and licensing by the sudden imposition of unsettled tort concepts would mean compensating a few at the expense of disrupting a vital tool of business. This could at the very least chill, if not smother licensing transactions and all the appurtenant benefits to society." Such a disincentive placed upon universities and other research developers of the nation's largest endowments for innovation could, in years to come, handicap this country's manufacturing development and worldwide competitiveness. As Goldman points out, even if licensors were protected from the financial burden of liability, "the very fact that liability could be imposed would cast an ominous and unnecessary cloud of uncertainty on each license arrangement, and stifle the innovation that the patent system is meant to encourage." In support of the policy issues addressed by Goldman, this paper attempts to show that courts may lend support through constitutional interpretations prohibiting impositions of product liability as a means to protect society against these "chilling" or even "smothering" effects.

Additional Theories for Consideration

Three theories of liability other than strict liability exist that potentially apply to patent licensors. The first theory is an implied warranty of merchantability and/or an implied warranty of fitness of the patented technology for the particular purpose of the licensee. Breach of the warranty occurs when that technology causes damage or injury. "Such an implied warranty is, however, generally associated with the sale of goods and not with the licensing of technology or provision of professional services."[7] In a second theory, the licensor may be

liable for making fraudulent misrepresentations that lead to damage caused by faulty technology. Here, the licensee must show (1) that the misrepresentations were material; (2) that the licensor knew or should have known they were false; and, (3) that the licensee relied on the misrepresentations to the licensee's detriment.[8] A third theory involving licensor liability is negligence. "For a licensee to recover he must prove the requisite elements of negligence, but often exculpatory contractual clauses will be effective in relieving the licensor of liability, particularly if the parties were in a relatively equal bargaining position."[9] These theories, although beyond the scope of this paper, must also be considered in performing a comprehensive licensor liability analysis.

Product Liability Law

A review of some of the key provisions of product liability law will help in understanding its application to patent and copyright licensing. The Restatement (2d) Torts, 402(a), defines strict (product) liability as:

(1) One who sells any product in defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
(a) the seller is engaged in the business of selling such a product, and

(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his product, and

(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

For product liability purposes, the term "product," usually pertains to tangible personal property ("a good, or chattel") and derives from the sales article of the Uniform Sales Act, now the Uniform Commercial Code and the common law of torts. "Product liability created and expanded an exposure to damages imposed by law upon the providers of products who were perceived as being able to distribute the risk of this exposure by price increases and, ultimately, by insurance providing the providers with protection against the exposure to liabilities -- products liability insurance."[10] Courts have extended the application of product liability law to intangibles, such as electricity. "It has been applied to natural products, such as a pet skunk, *Sease v. Taylor's Pets Inc.* 74 Or. App. 110, 700 P.2d 1054 P.2d 145 (1985) (pet shop strictly liable for injuries resulting from the sale of a rabid skunk). It has been applied to writings such as a mass-produced aircraft navigational chart, *Saloomey v. Jeppeson & Co.* 707 F.2d 671 (2d Cir. 1983), and to real estate fixtures such as a house, *Blagg v. Fred Hunt Co., Inc.* 272 Ark. 185, 612 S.W.2d 321 (1981)."[11] Further, courts have consistently extended product liability to one form of intangible intellectual property: trademarks.

However, courts have recognized constitutional limitations on their ability to impose product liability. For example, imposition of product liability on publishers of books poses a burden with respect to the first amendment too great for society to bear. Such constitutional limitations directly affect imposition of product liability on licensors of intangible intellectual property. Other factors used in determining whether product liability should apply depend not only on whether a "product" is involved, but also on such factors as constitutional limitations (freedom of speech), and whether or not the defendant is in the best position to spread the loss and prevent injuries.[12] Thus, courts have established boundaries on product liability law, prohibiting the extension of liability in areas where competing societal costs would offset compensatory damages to a plaintiff seeking redress for a faulty product. Universities performing technology transfer activities should pay particular attention to the boundaries set by the courts, because these boundaries will shield universities from the chilling and costly effects of product liability exposure.

Intellectual Property as Intangible Property.

To better understand the problem, one must first provide a working definition of the terms used. Typically, "intellectual property" is also "intangible property," as both terms generally comprise the group of patents and trade secrets, copyrights and maskwork rights, and trademarks. As few universities can effectively operate under trade secrets, and as maskwork rights can be analyzed similarly to copyrights, we will limit this group to trademarks, copyrights, and patents only. In considering the constitutional limitations of product liability, courts have clearly established a pattern, discussed below, which requires a further sub- grouping of intangible intellectual property. Such sub- grouping places trademarks in one class and places copyrights and patents in a second class. These two classes trace their status directly back to separate constitutional origins.

Trademarks

Trademarks derive from Article I, Section 8, clause 2 of the Constitution, which grants Congress the power to regulate interstate commerce. In 1946, Congress enacted the Trade- Mark Act (the "Lanham Act"), codified as Title 15, U.S. Code, 1051- 1127. The Lanham Act legally protects users of marks in interstate commerce. Importantly, Sections 5 and 45 of the Lanham Act require a trademark owner to retain actual control over the nature and quality of the product on which the trademark is used.[13] Because trademark law derives from relations between "related companies" and from congressional authority to regulate interstate commerce, trademark law inherently derives its validity from its relationship to interstate commerce. For this reason, trademarks uniquely represent a particular form of intellectual property quite distinct from the intellectual property represented by patents and copyrights.

The use of and need for trademarks as part of interstate commerce has led courts to apply product liability against trademark owners and licensors. For example, "Michigan has...subjected trademark licensors to vicarious liability for

consumers' personal injuries although the trademark licensor neither manufactured nor sold the product directly to the ultimate consumer."[14] See *Clark v. Texaco, Inc.*, 55 Mich. App. 100, 222 N.W.2d 52 (1974); *Johnston v. America Oil Co.,* 51 Mich. App. 646, 215 N.W.2d 719 (1974). See also *Sanders v. Clark Oil Refining Co.*, 57 Mich. App. 687, 226 N.W.2d 695 (1975).

Rosenblum et. al. aptly summarize three theories used by courts to impose strict liability in trademark licensing cases. In *Torres v. Goodyear Tire and Rubber Co.,* 901 F.2d 750 (9th Cir. 1990), the court imposed liability based on control exercised by the trademark licensor over the licensee. In *Connelly v. Uniroyal Inc.,* 75 Ill. 2d 393 (1979), "the court based the imposition of strict liability on the trademark licensing." And in *Carter v. Joseph Bancroft & Sons, Co.,* 360 F. Supp. 1103 (E.D. Pa. 1973), the court characterized the licensor as a "seller," upholding imposition of strict liability on the licensor.[15]

Notably, none of these trademark cases addresses a patent or copyright licensor in imposing strict product liability, and each of these courts found some significant degree of participation by the trademark licensor in introducing a product into the "stream of commerce." Finally, in each case where courts extended product liability to trademark owners or licensors, none reflected a requirement by the court to consider the constitutional limitations on imposing such liability. That is, none of the trademark cases reflected a competing need by the courts to withhold liability based upon concerns for freedom of speech or other important costs, such as a "chilling effect" on society as a result of imposing liability. Trademarks, then, form a type of intellectual property whose constitutional origins and legal developments provide no competing constitutional limitations prohibiting the courts from exposing trademark owners or licensors to product liability.

Copyrights

Whereas trademarks originate from Article 1, Section 8, *Clause 2* of the Constitution, copyrights (and patents), originate from Article 1, Section 8, *Clause 8*. This clause states that "The Congress shall have power ... to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." Congress enacted this provision for copyrights most recently through passage of the 1976 Copyright Act, which was significantly revised following the United States' accession to the Berne Convention in 1989.

A variety of court cases involve product liability plaintiffs seeking damages against copyright owners, publishers and authors. These cases explicitly demonstrate the competing interests of providing compensation to injured plaintiffs versus preserving freedom of speech and ideas. In *Winter v. G.P. Putnam's Sons,* 938 F.2d 1033 (9th Cir. 1991), mushroom enthusiasts became severely ill from picking and eating mushrooms after relying on information published in a book. The court stated *in dicta* that "[s]trict liability principles even when applied to products are not without their costs. Innovation may be inhibited.

We tolerate these losses. They are much less disturbing than the prospect that we might be deprived of the latest ideas and theories..." As the *Winter* court so exemplifies the notion of competing interests, it merits a more extensive quotation: "Although there is always some appeal to the involuntary spreading of costs of injuries in any area, the costs in any comprehensive cost/benefit analysis would be quite different were strict liability concepts applied to words and ideas. We place a high priority on the unfettered exchange of ideas. We accept the risk that words and ideas have wings we cannot clip and which carry them we know not where. The threat of liability without fault (financial responsibility for our words and ideas in the absence of fault or a special undertaking or responsibility) could seriously inhibit those who wish to share thoughts and theories..." Other courts have ruled similarly to the *Winter* court. See, for example, *Walter v. Bauer*, 109 Misc. 2d 189, 191, 439 N.Y.S. 2d 821, 823, (Sup Ct. 1981), where a student was injured doing a science project described in a textbook; the court held that the book was not a product for purposes of product liability law. See also *Lewin v. McCreight,* 655 F. Supp. 282 (E.D. Mich. 1987), where the court said that the publisher had no duty to warn of defective "ideas" in a book published by it, in view of the "weighty societal interest in free access to ideas."

Interestingly, courts have applied product liability law to writings, but not necessarily to copyrightable works containing the expression of ideas. For example, several courts have held that charts that graphically depict geographic features or instrument approach information for airplanes are "products" for the purpose of product liability law. See *Brocklesby v. United States,* 767 F.2d 1288, 1294- 95 (9th Cir. 1985) (applying Restatement (Second) of Torts 402A , *cert. denied,* 474 U.S. 1101, 106 S. Ct. 882, 88 L. Ed. 2d 918 (1986); *Saloomey v. Jeppesen & Co.*, 707 F.2d 671, 676- 77 (2d Cir. 1983) (applying Restatement for the purpose of Colorado Law); *Aetna Casualty & Surety Co. v. Jeppesen & Co.,* 642 F.2d 339, 342- 43 (9th Cir. 1981); (applying Nevada law); and *Fluor Corp. v. Jeppesen & Co.*, 170 Cal. App. 3d 468, 475, 216 Cal. Rptr. 68, 71 (1985) (applying California law).

The intangible intellectual property of copyrights grants exclusive rights to authors to encourage their free expression of ideas. In product liability cases where plaintiffs seek compensation from authors who express ideas through copyrightable publications, courts have clearly and consistently held in favor of authors, not to enforce the authors' legal rights under the Copyright Act but to protect the authors' (and society's) constitutional rights under the first amendment. No inconsistency exists where other courts have defined certain writings, such as navigational charts, as "products" for product liability purposes. For "writings" such as charts that failed to demonstrate a free expression of ideas, the courts had no competing constitutional or societal costs to consider when defining these writings as products in order to expose them to product liability. Moreover, the Copyright Act gives writings such as charts only limited protection because the critical aspects usually do not constitute original works of authorship.

Patents

This author has found no cases that subject patent licensors to product liability laws. However, conclusions can be drawn based upon the trademark and copyright rulings made by courts in product liability cases. To arrive at such conclusions, one should look again at a patent from a product liability viewpoint, and then compare the patent to copyrights and trademarks.

As stated in Article I, Section 8, Clause 8 of the Constitution, in return for disclosing a new invention to the "public," the government, as represented by the Patent Office, grants exclusive rights to inventors for limited periods of time. The Patent Act of 1952 more specifically defines the form of disclosure and the rights granted. When the Patent Office grants and issues a new patent, it also publishes the patented invention so the inventor's knowledge becomes available for all. As a disclosure document, the patent "must include a written description of the invention or discovery and of the manner and process of making and using the same, and is required to be in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which the invention or discovery appertains, or with which it is most nearly connected, to make and use the same."[16] In this manner, the patent document "promotes the progress of science." For product liability purposes, we can view a patent first as a disclosure document describing an invention and second as a legal instrument by which the government grants rights to a patentee (rights which a patentee may then license to another).

A patent derives from the same constitutional provisions as copyrights, so it should properly fall within the second class of intangible intellectual property as copyrights (while trademarks remain in the first class). And as an instructional document published by the government, one can consider a patent similarly to some copyrightable works; that is, as a "how to" book such as "How to Make a Better Mousetrap." "Even if that information (in a patent) is inaccurate, leading to hazards, or accurate and failing to adequately warn about hazards, it is nonetheless only information as opposed to a product itself."[17] In this context, court rulings on "how to" books should apply equally well to patents as publications. Turning then to recent court decisions, we find that in *Lewin v. McCreight*, the court raised, but did not answer, the question of "whether the imposition of a duty to warn (of potential defects in published material) upon publishers of 'how-to' books would pass muster under the first amendment." Following the *Lewin* question, *Cardozo v. True*, (Fla. App, 342 So. 2d 1053) also asked this question but went on to answer it by flatly refusing to extend a "duty to warn" of potential product liability dangers on publishers. The *Cardozo* court reasoned that such an imposition clearly would violate first amendment provisions.

If a patent as an instructional publication falls outside the reach of product liability law, what exposure might a patentee face under product liability law when the patentee licenses these rights to a manufacturer that ultimately produces a faulty

product from the licensed patent? We know that courts would weigh the constitutional issues of free expression against the issues of product liability, and we know that courts thus far have consistently ruled in favor of the greater societal interest to protect freedom of expression. Further, whereas trademark licensors may face full exposure under product liability law, courts have extended predictably different reasoning to patent licensors. In *Torres v. Goodyear Tire and Rubber Co.*, the court stated *in dicta* that "[t]he licensor of a patent is often in a somewhat different position (than that of trademark licensor). The (patent) licensor's contract is generally nothing more than a contract authorizing the use of an alleged patent, i.e., an invention. The product sold by the licensee is generally not sold under the trade name of the licensor of the patent. The general public is not in most instances relying on the licensor. *This is not to say the (patent) licensor may not participate to such an extent in the construction and sale of products made pursuant to a patent to justify the imposition of strict liability*." Thus, so long as the public has no reason to rely on the patent licensor for a product produced from the rights granted through a patent license, the patent licensor generally falls outside the scope of product liability law. Typically, university patent licensors can further sever reliance between themselves, their licensee and their licensee's future customers of the licensed products through the use of clauses in license agreements such as Warranty Disclaimers, Non-Use of Names, and Hold -Harmless/Indemnification clauses.[18] Using such clauses as part of a well written license agreement should firmly plant the burden for manufacturing reliable, safe products on the licensee as the manufacturer. The manufacturer properly shoulders the responsibility for producing safe products or bears the burden of compensating plaintiffs for damages under product liability law. As explained by one court "[t]he dangerous nature of an instrumentality would or should lead a manufacturer to foresee potential harm caused by the negligent design or manufacture of that instrumentality. Out of this foreseeability arose a duty to design and manufacture the instrumentality with due care. ...The operative theory of liability was negligence -- a duty arising in the manufacturer by virtue of the foreseeability of harm."[19]

The Legislative Solution

Finally, a legislative solution currently exists to protect patent licensors. The Department of Commerce published a draft Model Uniform Product Liability Act ("MUPLA") on January 12, 1979.[20] MUPLA seeks to hold manufacturers primarily responsible for design or manufacturing defects to limit product liability costs incurred by other parties in the regular commercial distribution chain, such as wholesalers, retailers and distributors. This model act essentially frees product sellers other than manufacturers from the threat of strict liability. "A product seller, other than a manufacturer, is subject to liability to a claimant who proves by a preponderance of the evidence that claimant's harm was proximately caused by such product seller's failure to use reasonable care with respect to the product."[21] Under MUPLA, a claimant would have difficulty qualifying a university patent or copyright licensor as either a manufacturer or product seller. MUPLA defines a product seller as "any person or entity that is engaged in the business

of selling products, whether the sale is for resale, or for use or consumption."[22] According to this definition, independent product designers who work for product sellers are not considered manufacturers if they are not otherwise engaged in the business of selling products. Thus, a mere licensor of ideas such as a university copyright or patent licensor should readily claim exemption as a manufacturer or product seller according to MUPLA.

In addition, MUPLA appears to exclude intellectual property when it defines a "product" as "any object possessing intrinsic value, capable of delivery either as an assembled whole or as a component part or parts, and produced for introduction into trade or commerce."[23] This definition supports the notion that a "mere" patent licensor does not introduce new products into the stream of commerce, but only makes the introduction of such products available to the public from a licensee.

Over the past decade, many states have enacted statutes modifying, and in many cases, limiting, traditional product liability rules. Washington state, for example, enacted RCW 7.72 in 1981 based largely upon the Model Uniform Product Liability Act. A complete analysis of product liability exposure for any particular institution, however, would require a review of product liability statutes pertinent to the particular state of residency of the institution.

CONCLUSION

Universities and other research institutions pursuing technology transfer by licensing their patent rights must carefully evaluate their transfer mechanisms in light of existing product liability law. Considering the cases above, if a particular university's technology transfer efforts center primarily on licensing patent rights, then that university may already realize protection from product liability afforded by the courts as a means to protect society's greater interests for the free expression of thoughts and ideas. In addition, a university may also enjoy statutory protection following MUPLA guidelines. The "mere" patent licensor, therefore, should carefully assess the need to seek further product liability protection through risk assessment mechanisms or by requiring licensees to carry expensive product liability insurance solely to indemnify the university.

On the other hand, universities also do not have *carte blanche* licensing freedoms with respect to product liability. Licenses that involve greater commitment by the university to produce tangible products, or situations that may allow the public (end- users) to place a reliance upon the university licensor for the end- product may introduce certain exposure to product liability. A university may risk exposure to product liability if it contracts with a licensee to perform additional work leading directly to the development of a licensed product, if it lends its name to be used with the final product, or if it starts a new company and participates in the development of the final product. University licensing of software may also expose the institution to product liability, as the transfer of software may be seen as directly releasing new products to end users.

Nevertheless, before heeding the warnings of those who urge caution on university licensing activities merely because trademark licensors suffer product liability exposure, university patent licensors should first understand the constitutional and legal differences between trademarks on the one hand, and patents and copyrights on the other. Before heeding the outcries of those who claim university licensing activities could bankrupt the entire institution, universities should first understand product liability laws and theories opposing imposition of liability on patent licensors. Most importantly, universities should understand that for the intangible intellectual property represented by patents and copyrights, courts and many legislatures already protect the free expression of ideas above the need to expose authors, inventors and their respective institutions to the chilling and smothering effects of product liability.

NOTES

1. Bayh-Dole Act, Public Law No. 96-517, 94 Stat. 3015 (codified as amended at 35. U.S.C. 200-212 (1982 & Supp. v. 1987)).

2. M. B. Goldstein, *"Technology Transfer and Risk Management"* (pamphlet), 9. NACUA (1990) (emphasis added).

3. Rosenblum and Fields, "Product Liability Risks of Licensing and How They Affect Commercialization of University Research -- Is It Time for a Legislative Solution?." Vol. III *Journal of the Association of University Technology Managers* 54 (1991).

4. Cowan, "Tort Liability of Patentee Licensors." Vol. 65 *Journal of the Patent Office Society* 87 (1982).

5. Goldman, "Strict Liability and Intellectual Property Licensors -- Keeping Closed a Can of Worms." Vol. 66 *Journal of the Patent Office Society* 630 (1984).

6. *Ibid.* at 650.

7. *Ibid.* at 639.

8. *Ibid.* at 640.

9. *Ibid.* at 640-41.

10. *Home Warranty Corp. v. Caldwell*, 777 F.2d 1455 (11th Cir. 1985).

11. J. Phillips, Product Liability in a Nutshell, 1 (3d ed. 1988).

12. *Ibid.* at 2.

13. Lanham Act [[section]]45, 15 U.S.C. [[section]]1127 (1964).

14. *Kosters v. The Seven-Up Company*, 595 F.2d 347 (6th Cir. 1978).

15. Rosenblum, *supra* note 3, at 46-48.

16. 37 C.F.R. [[section]]1.71(a) (1991).

17. Goldman, *supra* note 5, at 643.

18. Arthur Schwartz provides a useful "laundry list" of additional precautions a licensor might take to help ward off successful claims by product liability plaintiffs. Schwartz, "Licensing and Products Liability." Vol. 20 *Les Nouvelles* 41 (1985).

19. *Home Warranty Corp.*, *supra* note 10.

20. *Model Uniform Product Liability Act*, 44 Fed. Reg. 2996 (1979).

21. *Ibid.* [[section]]105(a).

22. *Ibid.* [[section]]102(b).

23. *Ibid.* [[section]]102(c).

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Technology Transfer With State Universities

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Technology Transfer professionals have long been aware of the federal constraints on commercializing university-developed technology. Restraints by state governments, often less detailed in the statutes, have been more difficult to identify, understand, and implement. Potential commercial licensees, often located in a state different from the state-university licensor, are likely to be unfamiliar with the state licensor's laws and regulations. Discussion of some of the issues that arise under state law, using the State of Texas as an example will, we hope, be helpful to industry representatives, and perhaps, to university representatives who may find themselves negotiating points they do not fully understand.

CONFIDENTIALITY

Everyone is familiar with the federal Freedom of Information Act. Many states also have open government or sunshine laws, which are applicable to state-supported universities, as agencies or arms of the state government. State universities in Texas, for instance, are subject to the Texas Open Records Act (Article 6252-17a, Vernon's Ann. Civ. St. [Supp. 1992]), and must, under circumstances spelled out in the statute, make all information that they collect, assemble, or maintain available to the public. This can affect the transfer of technology in a number of ways. Certainly, the license agreement itself must be made available if a proper request under the statute is made. But what about the subject matter itself? If patented or published in an academic forum, this may not be a problem for much of the technology making up the subject matter of the license. However, the know-how, often maintained as confidential, is a tougher issue. In Texas, in an effort to encourage and enhance technology transfer, the legislature, in 1985, saw fit to adopt an exception to the obligation of a state university to make certain information available to the public. That exception, codified in Section 51.914 of the Texas Education Code (Supp. 1992) provides: "In order to protect the actual or potential value, the following information shall be confidential and shall not be subject to disclosure under [the Texas Open Records Act or] otherwise: (1) all information relating to a product, device, or process, the application or use of such a product, device, or process, and all technological and scientific information (including computer programs) developed in whole or in part at a state institution of higher education, regardless of whether patentable or capable of being registered under copyright or trademark laws, that have a potential for being sold, traded, or licensed for a fee."

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In addition, this same article of the Texas Education Code provides statutory authority for a state university to contract with a research sponsor/licensee to keep that sponsor/licensee's proprietary information confidential. It states as a further exception to disclosure under the Texas Open Records Act: "(2) any information relating to a product, device, or process, the application or use of such product, device, or process, and any technological and scientific information (including computer programs) that is the proprietary information of a person, partnership, corporation, or federal agency that has been disclosed to an institution of higher education solely for the purposes of a written research contract or grant that contains a provision prohibiting the institution of higher education from disclosing such proprietary information to third persons or parties..."

Licensees need to educate themselves on the laws of the state in which the state university is located, which may or may not be similar to Texas.

EQUITY INTERESTS OF FACULTY

State-supported universities licensing technology developed by their faculty may have statutory restrictions on the ability of their faculty -- inventors of the licensed technology and non-inventors -- to hold either equity in the licensee company or participate in its management. The basis of the concern is the potential conflict of interest, where the faculty member may receive personal financial benefit from the commercial firm which has a licensing arrangement with the university, the faculty member's employer. In most states, generally speaking, state employees are prohibited from receiving a personal financial benefit from a business arrangement of their employer, an agency of the state. This is clear if you use a state-employed purchasing agent as an example. Few, if any, would argue against the prohibition of the purchasing agent receiving stock in a company that receives the bid and ultimately enters into a business arrangement with the state. Applicability of this prohibition to university faculty members often is not clear -- especially to the companies seeking to license technology. In fact, licensee companies firmly believe, many times, that the faculty member/state employee **must** receive a personal benefit or have a personal stake in the arrangement for it to succeed. This is an argument with which most university technology managers are familiar.

Texas, for instance, has a statutory code of ethics (Article 6252-9b, Vernon's Annotated Texas Statutes [Supp. 1992]) for all employees of the state, including university faculty members. It speaks in generalities about the obligations of the faculty member to the state as its ultimate employer. Other than stating its applicability to state university employees, the statute does not speak specifically to the type of fact situations in which state universities and faculty members find themselves when licensing technology. It speaks primarily in theoretical terms, such as, "It is the policy of the State of Texas that no state officer or state employee shall have any interest, financial or otherwise, direct or indirect, or engage in any business transaction or professional activity or incur any obligation

of any nature which is in substantial conflict with the proper discharge of his duties in the public interest." For these reasons, it was often difficult for state university technology transfer managers to explain in detail to a potential licensee the applicability of the statute to proposed licensing arrangements. Also using Texas as an example, there are no reported legal cases that interpret the specific applicability of this statute to university faculty in technology transfer situations.

In an attempt to meet the need of potential licensees and the desires of many faculty members, in 1987, Texas adopted Section 51.912 of the Texas Education Code (Supp. l992), which permits equity ownership by the **inventor** (and only the inventor) in a licensee-company that is licensing technology developed by the inventor from the university employer. Section 51.912 states that such equity ownership is not a violation of Article 6252-9b or any other statute, rule, regulation, or common law of Texas. By not mentioning in Section 51.912 other university employees who might be interested in owning stock in the licensee-company, it is generally considered that the statutory code of ethics prohibits it. For instance, UT Southwestern was negotiating with a group of investors putting together a start-up company for a license for university-developed technology. The investors wanted the chairman of the department who had been assisting in the business arrangement to receive equity in the start-up as well as the inventor. Due to the statutory provisions cited above, UT Southwestern took the position under the Texas statute that only the inventor could be a shareholder. Section 51.912, Texas Education Code, also provides that the faculty inventor may, upon factual finding by the governing board that no conflict of interest exists, serve as a member of the board of directors, or as an officer or employee of the licensee company.

Needless to say, other states have other statutes or common law that applies to their state universities. It behooves the company seeking to license technology from a state university to find out the constitutional, statutory, and regulatory provisions that control the issue of equity ownership and/or business participation by faculty members. Companies should always be cautious about equity agreements signed solely by the faculty member.

LIABILITY AND INDEMNIFICATION

Technology licenses generally contain provisions for the parties to be liable for the acts of their own employees, and not liable for the acts of the other party's employees. In most cases a university licensor will also ask the licensee to indemnify the university for acts of the licensee that may cause damage to the university. Most, if not all licensees, are accepting of this concept. However, there are occasions where the licensee may ask the university to indemnify it for acts or omissions of the university that might cause damage to the licensee. They may well successfully seek clauses of this type in routine business contracts with other commercial firms. Even some private universities may be accepting of this type of provision. However, the state-supported university may well be limited to the extent in which it may have authority to enter into an

indemnification agreement of this nature. Again, using Texas as an example, we can point out provisions in the Texas Constitution and case law that limit the authority of the university on this point.

Section 49, Article III of the Texas Constitution states that "no debt shall be created by or on behalf of the state. . . ." As pointed out in Texas Attorney General Opinion No. MW-475 (1982) this restrictive constitutional provision ordinarily will prevent a state agency, including a state university, from executing an enforceable indemnity agreement in favor of another party. It also points out that persons contracting with state agencies are bound at their peril to ascertain the limitations of the agent's authority and cannot recover to the extent the agent exceeds it. It is also clear that statutes giving a state university authority to carry out certain functions will not give authority beyond what the constitution allows. The constitutional limitation is read into the statute, which gives the state university the authority to act. As a practical consequence, this means that it is the law in the State of Texas that a state agency, including a state university, cannot be held liable for a contractual obligation concluded by an agent of the state in excess of his authority, and that no state agent can be given authority to incur or create a debt on behalf of the state in contravention of the constitution. Further, an indemnity provision negotiated by a state instrumentality in violation of law is unenforceable and void. Fortunately, it has been held that an invalid indemnity clause in an otherwise enforceable contract will not ordinarily invalidate the remainder of the contract or license.

In applying these legal concepts to the technology license to be negotiated between a state-supported university and a commercial firm, it becomes clear that the company cannot expect the university to be able to bear the costs, whether for damages or attorneys fees, suffered by the company because of the acts of the university or its employees. However, it should be noted that this teaches us that **by contract** the university cannot agree to bear the company's loss caused by the university's acts or omissions. There may, in the proper circumstances, be other legal remedies for the company to investigate in order to recover its losses allegedly caused by the university.

At UT Southwestern we attempt to exclude <u>any</u> indemnification of the licensee by the university. However, many licensees are insistent. For that reason, as a last resort, we will agree to such a clause if we can insert in any indemnification (of the licensee by the university) language that says the university will indemnify the licensee <u>only to the extent authorized by the Constitution and laws of the State of Texas.</u> In reality, we find that it is best to educate the licensee on this point. While it is clear that even if ignored in the language of the license, the law in Texas would still not make the state liable for indemnifying the licensee, it seems only fair to put the potential commercial licensee on notice about this point.

An example is: "Licensor, to the extent authorized under the constitution and laws of the State of Texas, indemnifies and holds Licensee harmless from any and all claims, demands, or causes of action, which claims, demands, or causes of action are asserted by any third party, and are caused or alleged to be caused

by reason of any alleged defect in the Licensed Technology, or by reason of any alleged negligence or act or failure to act of any employee or agent of Licensor."

Needless to say, licensees find this provision most disappointing. They feel each party should bear the costs of its own actions or omissions, even when the costs are the losses of the other party to the technology license.

We should also make clear that some state institutions have no fall-back position because they are precluded from including any language in any agreement, license or otherwise, that provides for indemnification by the university. Many others simply will not add this language to agreements because the institution, absent of an insurance policy to cover a loss, is in no position to absorb the risk.

INSURANCE

Often licensees suggest that the university purchase insurance to cover those potential losses that they cannot bear. However, in Texas, as in many other states, the legislature prohibits a state institution from purchasing insurance of this type. Accordingly, the answer to the indemnification dilemma is not simple. It is imperative that companies beginning to enter into negotiations with a state university ask about indemnification and insurance possibilities.

BUREAUCRACY OR INSTITUTIONAL STRUCTURE

Any potential licensee of state university technology must be aware that there are numerous levels of administration that must review and approve the business arrangement. In some states, there may be other state agency scrutiny of the deal that is made, even after the university approves it. The maze is easier to cope with if the company will seek to inform itself and understand the various levels of approval and tiers of scrutiny the agreement must survive.

Often potential licensees think that they can strike their deal with the faculty member-inventor. It is important to deal from the beginning with the administrative office delegated authority for technology transfer, as faculty are not authorized to contract on behalf of the university, nor are they always cognizant of the relevant laws and policies.

APPLICABLE LAW

The general legal rule is that the parties to any contract, including a license, may determine the applicable law by a clear manifestation of intention. That determination must be *bona fide* (i.e., not for the purpose of avoiding unfavorable law of the place of the making or the place of performing the contract). And we are sorry to tell you, according to expert Harry R. Mayers, "the choice must not be exotic, that is, totally unrelated to the context of the agreement." The courts have accordingly generally limited the parties in their choice of law to the place of making or the place of performance of the contract. The parties to a license agreement will have maximum likelihood of seeing their selection respected if the home location of the licensor is designated as the site of the applicable law. Most

often this will be closely connected with the important act of performance of the license.

State universities as agencies of the state are compelled to have the law of the state of their location govern the carrying out of the agreement. They also want their law to apply in any contractual dispute arising during the performance of the technology license. There is something abhorrent to a state government about having to be subject to the laws of another state. Fortunately, the general rules of law support that preference by the licensor. An example of a clause properly stipulating applicable law is: "This agreement shall be construed, interpreted, and applied in accordance with the laws of the State of Texas."

DUE DILIGENCE

A state university, as any agency of the state government, must abide by numerous laws and administrative regulations in contracting in relation to purchasing and selling the state's property. Real property to be sold or properties to be purchased often require compliance with complex bidding and advertising requirements. The transfer of intellectual property to the marketplace has often not been subject to the same intricate requirements. However, many state universities find that they need to perform what we will call "due diligence" in order to justify the technology transfer arrangements into which they enter. This can be seen by enthusiastic potential licensees as a waste of time at best, and an act of bad faith at worst, and at times it puts the technology transfer manager in a quandary. Does she negotiate in good faith with the first company approaching the university, or does she "shop" the companies capable of proper marketing of the technology, and then select the best. There are few rules that can provide exact advice to the technology transfer manager. General guidance and caution can be expressed.

It has been our experience that each case must be looked at individually. Perhaps the best advice is to consider this issue as soon as you have had the opportunity to determine exactly what the subject matter is. Begin to make your list of "possible licensees" immediately and make contact in an informal or formal way. The worst situation is if you have not considered potential licensees and have finalized a license with a company that in someone's estimation is not adequate. Having performed due diligence will protect the existence of the license you have negotiated and will protect you from undue criticism, but it must be handled carefully so that you do not alienate a company that contacts you early in the process.

DISPUTE RESOLUTION

Several methods of dispute resolution are highly touted today as ways to resolve problems that arise under any contract, including the technology license. The potential licensee contracting with a state-supported university must take care in assessing the authority of the university to resolve disputes in these alternative fashions.

For a number of years, Texas state-supported universities have excluded the commonly seen "arbitration" clauses, fearing that they could not be entered into constitutionally. The reasoning was that a state government cannot settle controversies "informally" without the sanction of the Governor, State Attorney General, Comptroller, and the courts. Fortunately, this position has evolved into one that is more palatable to all the parties involved: the clauses are acceptable if they provide for the sanction of a court of law before being put into effect. This is believed to be a safe position to take, as both statutory and case law appear to be favoring settlement of disputes in an informal manner. However, it does somewhat dilute the function of arbitration.

An example of a clause we might enter into as a state university in Texas is: "Any controversy or claim arising out of or relating to this agreement, or the breach thereof, including any dispute relating to patent validity or infringement arising under this contract, shall be settled by arbitration in accordance with the Patent Arbitration Rules of the American Arbitration Association, and judgment upon the award rendered by the Arbitrator(s) must be entered in any Court having jurisdiction thereof."

SUMMARY

State governments and their various agencies, such as state universities, are creatures of their unique constitutions and statutes. Little about business arrangements with them is uniform. Companies trying to license technology from these creatures often find themselves confused by the arguments. Sometimes non-lawyer technology managers find themselves confused by the arguments they are making on behalf of their universities. We hope this article clarifies these unique positions and facilitates the negotiation of technology transfer licenses between commercial firms and state-supported universities.

Biotechnology Licensing

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ABSTRACT

This paper discusses a number of factors in formulating the strategy of licensing biotechnology inventions and the fee structure of licenses. The factors to be considered in designing the licensing strategy include whether the technology is best licensed as patented property or as unpatented tangible property, how broad or basic the technology is, fields-of-use and sublicensing considerations, and the awareness of future improvements. The considerations taken in structuring the financial terms of a license agreement should be viewed as an overall package of license issue fee, milestone payments, annual payments, royalties and, in the case when the licensor is a non-profit institution and the license is exclusive, patent cost reimbursement. The issues and factors discussed should provide licensing professionals some insight into formulating the licensing strategy of biotechnology inventions.

STRATEGY

The strategy of licensing biotechnology should reflect several key features of the technology and the policy of the licensing institution. Policy can vary from one institution to another so that similar technology may be handled in different ways, depending on the goals of the institution and their prioritization. For the most part, we have assumed in this discussion that policy will be consistent with a licensing program that generates the greatest financial return over the commercial life of the invention. However, it is sometimes more desirable to generate the largest near-term return or to choose a licensee that will contribute compensation other than licensing fees, such as research support for the licensor or collaborative expertise. These policy issues will be addressed where reasonable, but we focus primarily on the key technology features and their impact on licensing strategy and the way that strategy is reflected in the fee structure.

Patented Property vs. Tangible Research Material - One of the first licensing decisions, particularly relevant for certain biotechnology inventions, is the determination of whether an invention should be patented or not. Naturally this has largely to do with how broad and defensible a patent can be obtained, but the determination should also take into account the possibility that the nature of patent coverage may not be very useful for the type of invention or that use of the invention may be difficult to determine or to monitor. Sometimes licensing as know- how or tangible material is more reasonable than obtaining patent protection. In other cases, it may be so difficult to monitor the use of the invention

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that the licensor is unable to provide licensees the assurance that unlicensed users will be pursued. This situation may make licensing, at least licensing for significant fees, untenable.

Examples are usually the best way to explain this issue, and one of the most frequently encountered examples is monoclonal antibodies. Here the greatest value to the licensee is often in having the cell line that makes an antibody that is useful in a particular product. If the cell line is made available to a licensee through a bailment agreement (discussed below) and not made available to others, often both parties are best served. This type of licensing strategy is particularly practical, as it is becoming more and more difficult to obtain patent coverage for monoclonal antibodies as the techniques for generating them become more and more reliable. Furthermore, patenting usually requires that the cell line be made available to the public when the patent issues and thus the control of the availability of the cell line may become labor-intensive. The patentee can contract a culture distribution agency, such as the American Type Culture Collection, to distribute the cell line upon request and to notify the patentee of parties who requested and received the cell line, but it then becomes the patentee's responsibility to determine whether any infringing use is made of the cell line.

Patent coverage is also of questionable value for cell lines or strains if they are known or expected to be not yet fully optimized for their intended use. In these cases one should investigate carefully with patent counsel whether or not patent coverage is likely to extend to derivatives of the strain in hand. If not, one may need to be prepared to file for additional coverage when the optimal derivatives have been made.

For these tangible properties, an agreement for the bailment of the biological material is often sufficient, and sometimes more valuable to the licensee, than patent protection. If access to a property or information cannot be limited, then licensing fees may have to be quite moderate to acknowledge primarily the licensor's facilitation of the licensee's acquisition of the technology at a time that gives the licensee a head start in product development.

In other instances, there may be several technological approaches that can achieve essentially the same result, permitting potential licensees to design around or avoid an invention that represents one such approach. Alternatively, the technological field of an invention may be moving so rapidly that the invention is likely to be superseded before it can be patented. If such an invention is embodied primarily in a tangible material or a defined package of information, it may be most appropriate to avoid the expenses of patent coverage and to license the invention at a price that acknowledges the savings to the licensee of gaining quick access to the material. This may be the case for certain strains or components of expression systems.

Bailment - A bailment is essentially an agreement under which the bailee/licensee is permitted to use the tangible property of the bailor/licensor

under defined terms and conditions. Intellectual property rights such as patents are not involved, although hybrid agreements that include both a bailment and a patent right are not uncommon in biotechnology licensing. These are often quite useful if the licensee wants access to a cell line that is or may in the future be covered by a patent. A bailment agreement can be an exclusive or non-exclusive agreement, and it should have the appropriate clauses on product liability, diligence, etc. There are some exceptional features that should be spelled out clearly in the agreement. The following is a brief discussion on these features.

- The title of the tangible property remains with the licensor. This is a particularly important point to state in the agreement to lay the foundation of the rest of the agreement, especially if it is an exclusive agreement.

- The permitted use of the tangible property is defined and restricted. The definitions of Licensed Product(s) and the Licensed Field-of-Use are particularly important. It is usually not intended that the licensee be permitted to sell the actual cell line or its progeny or derivative cell lines. Instead, the licensee is permitted to use the cell line and its progeny and perhaps its derivatives to manufacture some component of the product, often a protein. These intentions regarding use of the cell line usually necessitate the creation of a new definition, such as Licensed Cell Line, and separate provisions regarding rights in the Licensed Cell Line and Licensed Products. Derivatives should be addressed when appropriate, particularly if the licensee will not be permitted to make or use derivatives.

- The distribution of the tangible property by both licensee and licensor is usually restricted in order to prevent access by unlicensed competitors. Provisions may be included to permit transfer of a biological material for contract production to make a product. In a university setting, it may be necessary to allow the creators of the tangible material to distribute it to non-profit organizations for internal research use in order to preserve academic freedom. These transfers should be covered by written restrictive agreements and usually do not extend to for-profit organizations.

- The tangible material has to be destroyed or returned to the licensor upon termination of the agreement, unless continued use is to be permitted. The destruction/return provision or a requirement to maintain restricted access should survive termination of the bailment agreement.

Broad vs. Narrow - We use broad or basic here to denote those technologies that have many applications and usually deal more with methods for performing research or manufacturing products than with specific applications or products. These often could be utilized in a wide range of industries or for many applications within one industry. This type of invention is particularly prevalent in the biotechnology field, as the area is still relatively new and new techniques are being developed at a rapid rate.

Examples of broad inventions include: cloning vectors, expression systems or portions of these such as promoters or strains; cloning systems or methods; diagnostic formats such as the sandwich assay; generic compositions such as all monoclonal antibodies as a group, all chimeric or humanized antibodies or all antisense molecules of a given chemical type; and screening tests.

Narrower inventions have a more limited scope of applications and often describe a specific product. Examples would include a specific cloned gene or a diagnostic test or therapeutic agent for a particular disease.

The licensing strategy should take into account the fact that the basic technologies cannot usually be fully utilized by one company. They will often have to be added to other technologies in order to create a product, and those technologies may be owned by several institutions. A proprietary position for the licensee is often created by the choice of the specific application that is made and/or the addition of other technology that generates a specific product, not by the license to the basic technology. Thus an exclusive license to the basic technology is not needed to establish an exclusive market position and will often limit the potential royalty base for the licensor. Therefore, non-exclusive or fields-of- use licensing will usually maximize the return in the long run.

Sometimes the technology needs a champion to further develop it and fully reduce it to practice and this may argue in favor of some degree of exclusivity. In this case, whether the intended champion will be inclined to further sublicense or will instead maintain an exclusive position may be a concern and may affect the licensor's potential return. Splitting out well-defined fields of use to a limited number of exclusive licensees may ensure that each will have the needed incentive to fully develop the technology and that all fields of use are developed, but it may also discourage other potential licensees from getting involved in the technology and may encourage attempts to design around the invention rather than use the invention and take a license under reasonable terms. Any licensor of a basic technology often must make a significant commitment of internal resources to fully explore the potential of the invention. This commitment is less likely to take place if the licensee receives only limited rights or must commit to a restricted field of use before the technology can be fully developed or tested. It is also difficult to predict which fields of use some companies may develop in the future for an emerging technology, so limiting a broad technology to one or just a few licensees at an early stage may exclude significant potential returns from others who would take licenses at a later date.

The narrow inventions are generally more appropriate for exclusive licensing because they are often limited to a narrow range of products that can reasonably be handled by one licensee. But the exclusive vs. non-exclusive determination depends on one's assessment of the potential market and institutional policy. If the development costs relative to the market size would allow more than one licensee to have sufficient incentive to develop a product, one may want several licenses to increase the chances that a product will be developed or to encourage competition. Also, if an invention is relatively narrow and its

application will involve other technology such that the combination has broad applications or there are many possible combinations, exclusive licensing may be undesirably restrictive. For example, a license to a toxin that can be used by conjugation to a monoclonal antibody can only be used by any single company with the antibodies that company has for the applications that those antibodies address. Similarly, screening assays or assay formats can only be used by a company on the compounds it has or can obtain. Limitation by field of use can sometimes solve these problems but can also discourage broad investigation, particularly if fields of use are assigned early in the development of the technology.

Field of Use - It is also important to ensure that one has considered all reasonable uses of a technology in all fields of use. This aspect can be particularly difficult for biotechnology inventions, as many have broad applications or may have applications that have not yet been discovered. This is often the case when a gene has been cloned, but the biological function of the protein is not yet well characterized. Many biotechnology inventions have applications in a combination of the following areas: basic research reagents, components of diagnostics, reagents for process separations, agricultural uses (pesticides, fertilizers, growth modulators), or human or veterinary therapeutics. However, most companies do not handle more than one or a few of these business areas. Usually one wants to avoid granting rights that a licensee cannot or will not use and will not have the incentive to sublicense. For example, one would not want to grant veterinary uses to a pharmaceutical company with no veterinary business -- at least not unless the pharmaceutical will be packaging the licensed technology with some of its own. Lastly, whenever a field of use is limited, the definition of the field should be carefully constructed and reflect the expected applications and markets. Where possible, the field should be functional for the licensee and not unduly discourage others from taking licenses by discouraging exploration of a new technology.

Sublicensing Rights - Usually it is primarily marketing considerations that determine whether a licensee is given the right to sublicense. Is the company capable of supplying the entire market alone in all territories that have been licensed? Is the licensee capable of using all applications of the technology? But it is also important to consider how the technology itself will influence this decision. Will the licensee be adding technology of its own to provide a bigger package to sublicensees? This is very often the case with some of the basic technologies and with some technologies that require lengthy development. If so, does the licensee have a proprietary position around that additional technology so that only the licensee can provide the rights to the whole package? Will it provide manufacturing know- how or services for the sublicensee?

Especially in the case of broad technologies, it may be reasonable to allow even non-exclusive licensees the right to sublicense in order to reach all markets once a specific application has been made of the basic invention. Sometimes this is not a problem if the patent claims cover only processes or compositions that are

used in development. But sublicensing rights may be necessary if the claims cover compositions used in manufacturing, such as cell lines or the broad invention in the form it takes when a specific application is made. Such sublicensing rights are often necessary for basic technology licenses to biotechnology companies that have no marketing capability. For example, sublicensing may be necessary under a patent that covers all conjugates of a specific toxin when linked to any antibody if the conjugate is claimed as a composition. The direct licensee may intend to make a specific conjugate and develop it, but have marketing handled by a subsequent licensee, at least in certain territories. Another example is the case of a claim that covers an expression vector containing any structural gene (that which codes for the protein sequence). If a direct licensee uses the system to make a particular protein and sublicenses both marketing and manufacturing rights in the protein to another, the sublicensee will need rights under the vector patent to proceed with manufacturing even though sale of the protein itself is not an infringement of the vector patent.

In the case of exclusive licenses for technology with broad applications, it may be appropriate to require sublicensing. This is particularly attractive for the case in which an incompletely developed technology needs a licensor to develop and champion it, but will prove useful for many applications that will not be addressed by that licensee. Technology relating to production of biological materials is a good example. Often the technology has little chance of broad acceptance until someone applies it to one or several specific compounds, proves that it works economically on a commercial scale, and provides proof of the application to other potential licensees. The investment required to prove the technology's application may require an incentive commensurate with the right to handle further licensing and take a markup on the fees. And sublicensing, at least for other applications, may not be objectionable to the licensee.

Improvements - If an inventor continues to work in the same area of research as his original invention, a common occurrence in a university setting, improvement inventions are likely to be developed. The question then arises as to whether the improvements should be licensed or optioned with the initial invention. The answer often depends on the reasonableness of licensing without the improvements, whether the improvements would make the initial invention obsolete or just more powerful. The situation may also tend to point out that the initial invention may not be mature: it may be an invention in development. Even in this case licensing may be desirable, particularly if the licensee will fund continued development. Because the nature of improvement inventions is often such that they are dominated by the original invention, a licensor may not be able to license the improvement to any other parties other than the original exclusive licensee. This situation may be obviated by narrow field- of- use licensing for the original invention, but often the applications for both inventions are the same. Expression systems often fall into this problem area. While no magical general solution to this situation exists, a licensor should be aware of the potential quandary when structuring a license for the original invention.

On the positive side, a fairly broad grant of rights to basic inventions, including improvements, will probably increase the likelihood of broad usage and a potential royalty stream in the future. At the very least, an assurance (as a right of first refusal or an option) that a license will be available to improvement inventions will encourage companies to make the commitment to bring the initial invention in- house and devote resources to develop and use it. If the invention is a method, this commitment can become quite important to ensuring broad application and a larger potential royalty base.

FEE STRUCTURE

Relative Magnitude - Virtually all fees in a license have a relative magnitude that is determined by a combination of several factors. The various types of fees can be played against each other to reach an acceptable arrangement that meets the needs of both licensor and licensee, such that the same technology may be licensed under very different terms to different licensees, although all combinations are reasonable. That balance of various terms is really what the negotiation process is all about and is the reason that it is so hard to give firm guidelines on the exact fee level for any class of invention. But the application of a few basic rules should allow one to value any technology, often with several alternative packages of terms.

It is generally the case that fees increase with the following factors:

* Exclusivity

* Proprietary position (strength of patent coverage)

* Later stage of development (closer to market introduction)

* Increased certainty of success (linked to stage of development, but not solely)

* Increased market size

* Increased geographic territory (fees should relate to the market size for each territory)

* Lack of competition

* Profit margin in the field of application

The most customary fees are as follows:

* License issue fee (due on signing)

* Milestone or benchmark payments (due by certain dates or on the occurrence of certain events)

* Yearly fees

* Royalties

License Issue Fee - In addition to the above features, the license issue fee is often related by necessity to the licensee's ability to pay and is therefore balanced against the other fees due in the license. Because of the immediacy of the payment, this fee can substantially influence whether licensees sign up willingly or only reluctantly and thus can be used to establish the desired strategy. Particularly for basic or undeveloped technology, a modest license issue fee can be used to encourage broad non-exclusive licensing and testing of the technology and may avoid the need to use litigation to bring infringers into compliance. For many biotechnology inventions that require substantial development or that must be combined with other technologies to create a product, it is often most reasonable to encourage licensing by backloading the fees: keep the issue fee modest and raise other fees substantially as the technology proves its feasibility in the hands of the licensee or licensor. Moderate fees for basic nonexclusive licenses can encourage broad experimentation with the technology and increase the chances that a broad royalty base will bring a higher long-term return.

High issue fees are almost always associated with substantial exclusivity for the licensee and therefore are more often used with narrow rather than broad technology. Even for a breakthrough basic technology, the investment required to determine how well it works or to find an appropriate specific application may argue in favor of modest issue fees to encourage broad licensing and usage. More substantial fees can always be required upon achievement of milestones that indicate successful application. The definition of these benchmarks should be carefully chosen so that they are appropriate to the field of use.

Milestone Payments - Milestone payments are used primarily to compensate the licensor for value in an invention that is not yet proven at the time of licensing, or to ensure diligence on the part of the licensee. Thus, they are usually coordinated with the issue fee and are paid out as the development of the invention demonstrates its value. These can be very creatively designed to address concerns of both licensee and licensor and should be triggered by events that both agree indicate increasing value to the licensee. For exclusive licenses, milestones can also compensate the licensor for decreasing value in case the license is returned to the licensor and a new licensee must be sought (lost opportunities). It is important to realize that the licensee will expect consistent rationale in the structure of licensing terms. Consequently, it is not usually reasonable to demand diligence payments or reporting obligations for a non-exclusive license in which the licensor is not losing another opportunity by granting the license, but regular payments can be justified as compensation for the value provided to the licensee. Whether timed payments are an appropriate form for such compensation depends largely on the other fees that are charged.

For broad inventions, particularly if a modest issue fee is chosen, it may be reasonable to have milestone fees due for each specific application of the technology when the application reaches a stage indicating likelihood of success. For example, a license to an expression system could require a milestone

payment for each application that is scaled up to sufficient level to support clinical trials (for pharmaceuticals) or field trials (for agricultural compounds) or upon market introduction. A basic technology relating to antibody engineering could require a payment for each engineered antibody that reaches clinical trial stage.

Yearly Payments - Yearly payments not related to achievements are often used as compensation for a technology that is not easily monitored by achievement or that is used only in research applications distant from development of a product. These are often creditable against royalties, particularly if the fees are substantial. In some cases, these payments may even replace royalties. This form of compensation is often appropriate for technology relating to screening assays or methods that help to identify another composition that is the ultimate product. It is also used with research technology if patent claims do not cover the ultimate product, but cover methods used in identifying or designing the product or methods that have no direct, perhaps not even an indirect, relation to products. If the connection to product is quite distant, it is often hard to justify royalties, since the licensee contributed most of the inventiveness relating to any particular product. However, a "toll" fee for the privilege of using the invention for research can be easily supported, and the magnitude should depend on the novelty and power of the invention being licensed.

Other types of toll fees may relate to the frequency with which the invention is used, such as a fee for every one thousand assays performed using a particular screening procedure. The practicality of measuring frequency of use and the licensor's ability to detect or monitor any such parameter should be considered in choosing between a yearly and a tolled payment. A cumbersome procedure or one that violates the licensee's other proprietary rights and obligations can discourage licensing.

Royalties - Royalties are usually used as the most direct way to connect the licensor's compensation to the successful application of a piece of technology. In setting a royalty rate, the most relevant issue is a determination of the magnitude of the licensor's and licensee's contributions to a product. In the biotechnology area this can be particularly difficult because the form of the final product is often not known at the time a technology is licensed. Particularly for university inventions, the technology often needs substantial additional development as well as the addition of many other technologies before a product emerges. As so many of the inventions relate to basic methods for designing or identifying products, the licensee is often worried about stacking royalties that may make a product unprofitable. At the time of licensing, it may not even be possible to estimate reliably what these royalties will be.

For these reasons, biotechnology inventions, especially those of a basic nature, often must carry fairly modest royalties, usually less than 6 percent, for example, and often much less. The licensee often will contribute substantial expertise and other technology in the development of the invention and thus will not feel that large royalties are justified. Non-exclusive rights to technology that contributes only a portion of a final product are often no more than 0.5 to 3.0 percent. On the

other hand, technology that is close to market introduction and addresses a large and/or high profit market may bring royalties well in excess of six percent.

One way to accommodate the uncertainties is to provide for adjustments to royalties if third party royalties are incurred. If this is done, it is usually best to provide a cap or ceiling for the licensee and a floor for the licensor. Otherwise, the adjustments may result in royalties that go well above or below what seems reasonable. Usually a top royalty is chosen and is discounted by the amount of third party royalties or by a fraction of such royalties until the floor is reached. If the licensor feels that the top royalty leaves room for additional royalty obligations, the licensor can insist that the discount not be applied unless the total royalty goes above a set limit that exceeds his top royalty.

Many biotechnology products have multiple components, not all of which are covered by the licensed technology. If net sales are used as a royalty base, adjustment should be made for the non-covered components if they contribute substantially to the product. The most common formulas provide that the royalty base (usually net sales) or the royalty rate be multiplied by a fraction related to either (1) the relative proportion of components in the product that are covered by the license, or (2) the proportion of the total manufacturing costs that pertain to the covered components.

In those cases in which several potential applications of an invention are licensed, different royalty categories for different applications are often necessary. This relates to the need to anticipate all reasonable uses of a technology. Such consideration directs the design of an appropriate royalty structure and avoids the very difficult situation in which a company is granted rights to an application for which no royalty or other compensation is contemplated in the license agreement. If the rights are not reserved for the licensor in the grant, then their application should be contemplated in the royalties and other financial terms. For example, a licensee might take a cell line that produces a mouse monoclonal antibody and clone out the antibody gene, then use the gene to create a chimeric antibody gene (part human and part mouse). Further modifications might result in a chimeric gene linked to a protein toxin gene which would result in production of a fusion protein. Clearly the original antibody is the creation of the licensor, but the chimeric gene and, to an even greater extent, the fusion gene, are the result of additional work by the licensee. A licensor will want to make it clear in the license agreement that the more developed products were intended to be covered by the agreement, but may need to provide a royalty concession to the licensee for these products relative to the original antibody. A royalty that decreases with the addition of licensor contribution to the product provides appropriate acknowledgment of the licensor's efforts. In situations such as this, one should discuss an invention with its inventors or other technically informed people in order to fully understand the potential applications of the invention and provide for them in both the granting clause and the financial terms.

Clearly, if all of the above royalty adjustments are applied to the same technology, the royalty calculation and license language can get so complicated that disagreements are likely to arise regarding the royalties that are due. When clauses such as these have the potential to overlap, one should clearly state within the license which clauses have precedence or in what order they should be applied.

In addition to a royalty rate, an appropriate royalty base must be clearly identified. While net sales of product (usually defined as Licensed Product covered by patent claims) by the licensee are the most common royalty base, this is not the only choice nor is it always the most appropriate. Sometimes the licensee will be offering a service, not a product, so that sales of a non-existent product are irrelevant. These issues should be carefully addressed in both the definitions and the granting clause, as well as the description of how royalties will accrue. One must be wary of always using the same definitions in both the grant and royalty clauses, because these definitions are sometimes not applicable to both situations. If the licensee will be selling an intermediate product that will be further modified or packaged, perhaps with other components, the licensee's sales may not reflect best the value of the invention. In this case, sales by the intermediate purchaser may be a more appropriate royalty base (if such sales figures can be obtained) or the royalty rate may need to be raised relative to what it would have been for the seller of the final product.

Although most patent licenses provide for royalties for the life of the licensed patents, no such customary term of royalty obligation exists for unpatented inventions. This term usually relates to the expected life of the product and the term over which the licensor is providing a competitive advantage in the form of quick access to the licensed technology. Fairly customary royalty terms for unpatented cell lines, including those that produce antibodies, are five to ten years from market introduction or licensing, although both longer and shorter terms are sometimes appropriate depending primarily (1) on the extent to which the technology can be maintained as proprietary and (2) on its competitive significance. If one runs this term from the licensing date, it is important to have a relatively accurate prediction of the date for market introduction and some comfort that royalties will accrue for a reasonable time. It may be wise to start the running date as of the date of market introduction or to negotiate a reasonable but significant minimum annual royalty that will initiate in the year of the expected market launch date. In licenses that combine patented with unpatented technology or with technology that may or may not obtain patent protection, it is important to specify the royalty term for each type of technology separately. Be aware that the term of royalty obligation may become unclear if more than one technology or product is licensed under a single agreement and the royalty term is linked to the market introduction of the product. It is important to define whether market introduction starts with the first product only or with each product.

Patent Costs - One of the terms a licensor (particularly a university or nonprofit) often imposes is the obligation to cover patent costs for the licensed invention. If the licensee agrees to this, one should expect that he will at least insist on paying only a portion of the total costs if he is not obtaining an exclusive license. If the total number of licensees is not known when the first license is signed, an estimate of the expected number of licensees should guide the split of fees. Alternatively, credits of patent cost payments can be applied against other future fees to be paid under the license. In this way, over time all licensees are made whole for the patent costs, even if the amount varies from licensee to licensee, and the licensor does not have to cover the costs up front.

CONCLUSION

Biotechnology licensing demands some unique and creative approaches by licensing professionals, particularly because the technology is often capable of self-replication, the final product may require several licenses for commercialization, and the technology is often licensed at early stages of development, even before the precise nature and utility of the product is known. Because of these features, certain sections of the license agreement are often quite technical but critical to the interpretation of the agreement. The overall strategy for licensing and the way in which key terms and the fee structure are used to achieve that strategy can significantly influence the degree to which the technology is ultimately used and the return to the licensor. In light of the novelty and the lack of precedence, one must predict the future and try to do the best possible. But the extraordinarily high level of uncertainty also generates the excitement and challenge of licensing in the rapidly-moving field. We are still learning from our successes and mistakes.

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