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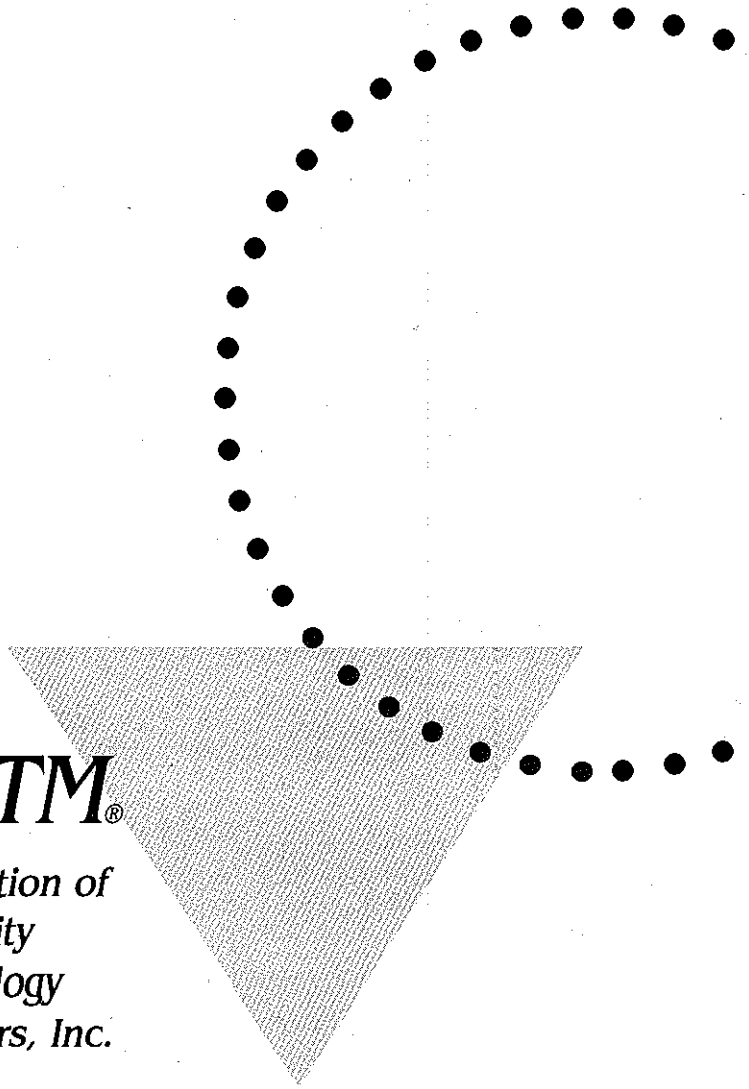

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JOURNAL OF THE
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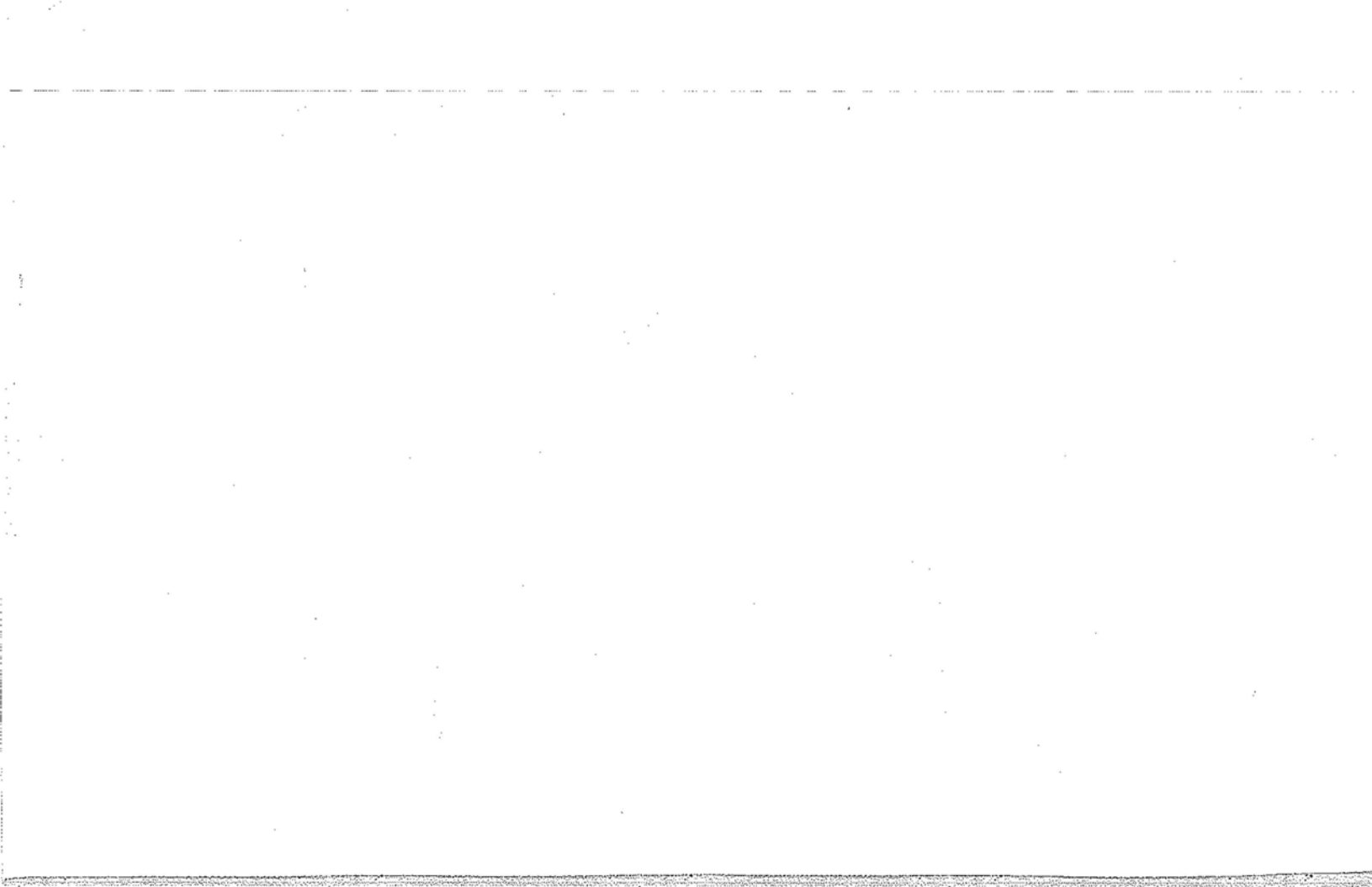

Editor's Preface

In this tenth edition of the *AUTM Journal* (and the seventh in which I can claim my involvement in an editor capacity) we bring a group of broad-interest articles to our membership. In harmony with our mission of bringing the AUTM membership a continuing flow of useful information that can stand the test of time, the articles contained in this volume address the fundamentals and implementing devices used in the administration of university intellectual property.

Two instructive articles on similar subjects by returning authors Stanley Lieberstein ("Relevant Concepts in Determining Difficult Disputes Over Ownership") and Kathleen Terry ("Implications of Joint Ownership of Patents") focus on forming a strong foundation for determination of ownership in order to avoid problems in your technology transfer program. Their examples address ownership in general and university joint ownership in particular.

Sheldon Burshtein, another previous contributor, weighs in to address a topic of great interest to university members on both sides of the Canadian border, with "What is a 'University' for 'Small Entity' Purposes in Canadian Patent Law?" This paper examines case decisions that could provide support for a Canadian institution to claim small entity status, allowing it to pay reduced patent fees.

Another pair of "twin subject" articles finishes this volume of the *Journal.* David Parker graces our pages again, this time with co-author Nicole Stafford, with a piece called "Biotechnology Research & Patent Infringement: Should Research Be Exempt from Charges of Patent Infringement?" Martin Simpson writes on "Use of Bailment in Transferring Technology from a University." The easy writing style of the former authors addresses a conversation point that continues to be discussed in university settings and gives our members a host

of valuable notes the reader can use as the basis of substantive continuing research into the subject. Mr. Simpson's love of the history of law is apparent in his interesting analysis of a lesser-known kind of licensing that is vital to the mushrooming biotechnology industry. He shows us why the venerable Roman tool of bailment is sometimes preferred to patent licensing in the relatively new context of biotechnology licensing and changing patent protection.

Many thanks to all the authors for their efforts and for their attention and time throughout the editing process. We encourage our readers to submit original papers on topics of interest to professional technology managers. Those contemplating writing an article or a letter to the Editor are asked to contact the Managing Editor for content and review procedures.

Beatrice Bryan, Editor
September, 1998

Relevant Concepts in Determining Difficult Disputes Over Ownership

Stanley H. Lieberstein*

INTRODUCTION

This paper explores the facts influencing a determination of ownership. It offers a specific case study and highlights findings from relevant cases to describe the important points to be considered when reviewing ownership. The paper concludes with a recommendation to obtain signed employment agreements that define respective rights to ownership of inventions. The reasons behind this recommendation are outlined throughout this article.

SAMPLE CASE STUDY

One day your client presents the following scenario and asks for your opinion. The client had contracted to solve an important technical problem for a major manufacturer. Your client then hired a consultant who had expertise in precisely the most important aspect of the overall project to consult on this project. The consultant was a professor at a distinguished university.

The consultant was hired and paid during the course of the project. Correspondence between the consultant and your client

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reveals that the consultant knew from the outset that he was engaged to assist your client in a project for the manufacturer. There was no written agreement between your client and the consultant.

After the project was successfully concluded, the consultant, on his own, obtained a patent on an invention made by him during the time he worked for your client on the project. He then wrote to the manufacturer demanding royalties for the use of his patented invention. The manufacturer turned around and sent the demand to your client stating that this matter was your client's problem. The manufacturer said that it had paid your client a flat fee for undertaking that project, and therefore, had implicitly paid for the right to use any invention that arose from the project your client had undertaken for the manufacturer.

Query: In your opinion to whom does the invention belong? Can your client assert title and seek an assignment of the patent? What are the rights of your client with respect to the consultant and the manufacturer? Can the manufacturer continue to use the invention without a license from the consultant? What rights does the university have?

CONSIDERATIONS

In order to provide your client with a well-reasoned opinion, it is useful to step back for a moment and review certain fundamentals, to gain an appropriate sense of perspective.

At the outset with regard to licensing and the transfer of rights to technology generally, it is essential that we recognize that ownership rights and the right to grant others technology rights cannot be determined in a vacuum.

The license you last drafted for a client may be a beautiful example of legal craftsmanship, but may be meaningless if there is a legitimate cloud on the ownership rights to the underlying technology. So, when called on to draft or review a license or

any agreement that may involve the transfer or the right to use technology, it is always worthwhile to determine whether there may be any underlying issues affecting the rights of the parties, particularly the right of the granting party (licensor) to make that grant.

For example, is it possible that a third party may have some rights that may interfere with the enjoyment of the rights or license being granted? How did the technology arise? If from a sponsored project, who was the sponsor? What terms of agreement governed the sponsorship? Who are the inventors and where are they now? Have the inventors made any independent agreement transferring rights to the technology? This issue is particularly sensitive when acquiring rights from universities.

The principle of *caveat emptor*, which applies as a rule to virtually any situation, is particularly appropriate to the determination of ownership issues in licensing and technology transfer. All too often discoveries are made by faculty members or graduate students who take jobs outside the university and then assign rights to the same technology or a variation thereof, which was first created at the university. And no matter what the university policy, nor how clearly it is written, universities are not geared to fully police their faculty and graduate student body. Indeed, at times the licensor (or seller) may be acting in good faith, unaware that others may have acquired rights to the same technology from the same source. A faculty member eager for a grant to support a research project may (perhaps unwittingly) sign agreements transferring his or her rights in new inventions or products to more than one sponsor. The university may later find itself in conflict with one or more companies each asserting rights derived from two or three key investigators who participated in that project.

With that principle in mind, let us now review some cases that illustrate the rules governing the use and ownership of inventions and see how those rules may apply to the fact

pattern posed earlier concerning your client, its former consultant, and the third party manufacturer.

THE "EMPLOYED-TO-INVENT" RULE

A classic case in this area—a case that is still relied on and cited even today—is one that was decided by the Supreme Court in 1924, known as *Standard Parts Co. v. Peck.*[1] In that case, William J. Peck had been hired by Mr. Hess of the Hess-Pontiac Spring and Axle Company with a written agreement dated August 23, 1915. In that agreement Peck promised to "...devote his time to the development of the process and machinery for the production of the front spring now used on the product of the Ford Motor Company." The agreement provided for payment to Peck but was silent as to ownership rights.

Subsequently, Peck developed certain machinery and was paid by Hess in accordance with the contract. Thereafter, Hess sold his company to the Standard Parts Company. Peck obtained a patent on his own and later contended that the Hess Company, which paid for his services, had acquired a shop-right only, i.e., a personal right to use his machinery free of the payment of royalty, a right that is not transferable. That, incidentally, is the way a shop-right is generally characterized, personal in nature, a royalty-free right-to-use, and non-transferable. Remember, the contract Peck signed did not provide for the transfer of any rights. And according to the opinion of the Sixth Circuit Court of Appeals in that case, unless there is a contract controlling ownership rights, the employer had only a license to use the employee's inventions.

The Supreme Court reversed the Sixth Circuit Court of Appeals finding that the process and machinery discovered by Peck was "...nothing more than he was engaged to do and paid for doing..." The principle of the *Standard Parts Co. v. Peck* case is that when an individual is specifically hired to solve a problem such as Peck was, to develop a process and machinery for the

production of automotive springs and he is paid for that work, then any invention that arises is owned by the employer, even without a written contract governing ownership. The *Standard Parts Co. v. Peck* case is sometimes referred to as the basis for the "employed-to-invent" rule.

But what constitutes an employment to invent? When is an employee hired to invent?

In the case of *Liggett Group, Inc. v. Sunas*,[2] decided by the North Carolina Court of Appeals in 1993, a lower court's grant of summary judgment was reversed by the Court of Appeals because, among other things, the evidence did not establish that the employee, Sunas, was hired to invent. The Court of Appeals said that Sunas was not initially hired to invent and that there was an issue of fact as to whether Sunas was later assigned to experiment with a view toward making the invention.

The invention in that case was a quick-aging process for enhancing the aroma of tobacco. In the absence of a written contract, the North Carolina Court of Appeals noted that for the employer to own the invention, the employer would have to establish either (1) that it had hired the employee for the express purpose of making the invention in question *or* (2) that during the course of employment it had assigned the employee to engage in work "with the view of making" the invention. That is, the invention would have to be the direct result of work to which the employee was assigned in the course of employment and for which the employee was paid. The court said that there was an *issue* here *for the trier of fact* as to whether the invention was a product of the work to which Sunas had been assigned by the employer, Liggett.

THE RIGHT TO USE: "SHOP-RIGHT"

An important distinction worth noting is that the question of whether your client has a *right to use* technology created by its consultant is *independent* of whether the consultant was hired to

invent. For example, in the *McElmurry v. Arkansas Power and Light Co.*[3] case decided by the Federal Circuit in 1993, the consultant, Harold L. Bowman, made an invention in the course of his work as a consultant, for which he was hired and paid. After being engaged as a consultant, Bowman suggested a new design for a "level detector" that determined the "level" or amount of fly ash removed from gas emitted by coal-fired boilers used to generate steam. Once more, there was no agreement governing ownership and *Bowman obtained a patent on his own* and assigned it to a partnership that he formed with McElmurry and Mitchum, which they called "White River Technologies."

At first, White River acted as a contractor for Arkansas Power and Light (AP&L), installing the level detectors at a great many locations. Later, however, after Bowman's consulting contract expired, Arkansas Power and Light continued to install the same detectors but hired outside contractors who were less expensive than White River. That's when White River sued Arkansas Power and Light for infringement of the Bowman patent.

There is no indication from the opinion of the Federal Circuit, written by Judge Rich, that Arkansas Power and Light ever argued that it *owned* the patent and there is no discussion indicating that ownership was an issue. Apparently, Arkansas Power and Light was satisfied to contend that because they had engaged Bowman as a consultant and paid him for his services, they had a shop-right. The opinion of the Federal Circuit Court suggests in a footnote that Bowman may have had the idea for the level detector prior to his employment with AP&L.

The Federal Circuit determined that a shop-right applied in that case. The court's opinion cites a number of cases describing the genesis of the shop-right rule, explaining how it is derived from equitable principles, such as an employee or consultant's use of the facilities, resources and supplies of the employer, and observes that a shop-right is a form of equitable estoppel. The

case suggests strongly that it would be inequitable for Arkansas Power and Light to have to pay royalties to Bowman, having already paid him for designing the level detector. The court also observes, again in a footnote, that it does not matter whether Bowman was hired as an employee in a conventional sense or as an independent contractor, at least not for purposes of determining the issue of shop-right. The Federal Circuit defined the shop-right as a non-exclusive, royalty-free right to use the invention of Bowman, regardless of his status as an independent consultant.

A UNIVERSITY CASE AND PROBLEM

With these two concepts in mind, namely "employed to invent" and "shop-right," let's turn to technology transfer agreements with universities, which have become increasingly prevalent. An example of just how murky the water can become in that situation is the case of *University Patents, Inc. v. Kligman*.[4] The District Court for the Eastern District of Pennsylvania in 1991 denied a motion for summary judgment by the defendants, Johnson & Johnson, and the individual inventor, Albert Kligman. The defendants argued that the University of Pennsylvania, which employed Kligman, and University Patents had no enforceable rights in the invention.

In this case, Professor Kligman had invented a preparation for photoaged skin that he licensed to Johnson & Johnson. The invention involved the discovery of Vitamin A acid or retinoic acid for the treatment of acne. University Patents, an assignee of the University of Pennsylvania, brought suit on behalf of the university, claiming ownership of the invention.

The facts indicated that the University of Pennsylvania had a policy governing ownership of inventions made by its faculty members and according to the university its policy applied to Professor Kligman. Professor Kligman, whose work was funded through consulting agreements, claimed that the university's patent policy was never sent to him.

In fact, Professor Kligman had written a letter to an official of the university stating that he had developed this topical preparation for the treatment of acne on his own time with his own personal funds. Professor Kligman hired a patent lawyer with his own money and while the patent application was pending, Professor Kligman signed a license agreement with Johnson & Johnson, stating that he, Professor Kligman, was the sole owner and was free to license the invention.

A central issue in this case was whether the university patent policy was binding and obligated Professor Kligman to assign his rights to the university. The court cited *Standard Parts Co. v. Peck* in support of the principle that in the absence of a written agreement governing ownership, for the employer to own the invention, it had to arise in a situation where the employee was (1) hired to make that invention or (2) assigned to solve a particular problem during the course of employment and the invention was the result of solving that problem. In the *University Patents* case, Professor Kligman had never signed an agreement with the university and disputed the application of the university patent policy to him.

In its opinion, the District Court of Pennsylvania referred to an earlier case known as *Aetna-Standard Engineering Co. v. Rowland*,[5] decided in the State Court of Pennsylvania where the employee, Rowland, had been hired as an engineer and during the course of his employment was assigned to a particular project. In the course of his work on that project, he completed a table design and he signed a disclosure document as a joint inventor with his supervisor and also signed an application for a patent. Subsequently, the engineer was laid-off and then when he was asked to assign his interest in the patent, he refused. The employer, Aetna-Standard, tried to compel an assignment but the Pennsylvania Superior Court refused. In that case, the Pennsylvania Superior Court found that the engineer was hired as a "general staff engineer" and had not been recruited specifically to design the table, and received no special compensation for his work on the project. Moreover, he had no

express agreement to assign any inventions and the table design was not the result of his specific assignment to any problem for which he had responsibility. His employment was held to be too general to justify implying an obligation to assign the table design in the absence of any written obligation to do so. In short, the state court in *Aetna-Standard* found that the engineer, Rowland, had not been hired to invent nor was he assigned during the course of employment either to make the design in question or to solve a problem that directly gave rise to that new design.

Returning to *University Patents, Inc. v. Kligman*, the federal district court found that Professor Kligman had never been requested by the university to sign either a patent agreement or disclosure form with regard to the acne invention. Furthermore, the court observed that it was not clear that any reasonable person receiving the handbook containing the university's patent policy "would have understood himself to be bound by the terms of a form agreement he never executed."

In the course of his depositions, Professor Kligman testified that before the lawsuit he had no knowledge of the university patent policy and did not believe that the policy applied to him. The court, however, noted correspondence between Professor Kligman and the university that may have led the university to believe that the professor was aware of the policy and would be bound by it. There was also some evidence that Professor Kligman had made use of or based his invention on university resources that were available to him. For that reason, the *court denied summary judgment* leaving it to a jury to determine whether there was evidence sufficient to find an implied contract to assign the patent from Professor Kligman to the university.

In a great many universities, there are patent policies that the administration does its best to disseminate widely. There is at least one problem, however. Many, if not most, of those universities do not require their faculty to sign any agreement

that is specifically tied to their patent policy. Indeed often the university policies are distributed as part of a handbook containing many other policies relating to other subject matter and there is no requirement that the individual even acknowledge receipt of the handbook much less the specific patent policy. So there is a legitimate question as to the extent to which an obligation to assign patents contained or perhaps buried in a university handbook may be applicable to a faculty member. And there is an even more open question as to the rights of any graduate student who may have assisted a faculty member, or may have made an invention in the course of his or her graduate work under the supervision of a faculty member.

THE IMPLIED CONTRACT

The law implies a contract governing title, if there is no written agreement, when the circumstances strongly indicate that the invention was a direct result of the sponsored research. For example, in *Teets v. Chromalloy Gas Turbine Corp.*,[6] the Federal Circuit Court of Appeals said:

> An implied-in-fact contract is an agreement "founded upon a meeting of the minds, which, although not embodied in an express contract, is inferred, as a fact from conduct of the parties showing, in the light of the surrounding circumstances, their tacit understanding."

In the *Teets v. Chromalloy* case, Teets, the inventor, asserted title to an invention he made while an employee of Chromalloy. Teets argued that the invention was made at home and that he had not been hired to invent nor was the invention a part of his responsibilities. The court, however, recognized that during the course of his employment (but not initially), Teets was assigned the role of Chief Engineer on a project, that he devoted more than seventy percent of his working time to their project, and that the invention was part of and directly within the scope of that project. Therefore, the court awarded title to the employer, Chromalloy. In addition to outlining the circumstances under which a court will imply a contract to transfer title, this case

illustrates the importance of understanding the scope of the project and the work assigned to the inventor.

DETERMINING THE SCOPE OF THE WORK OR PROJECT AND THE SCOPE OF THE INVENTOR'S RESPONSIBILITIES

In a classic case known as the Gatorade case, Dr. J. Robert Cade, an associate professor of medicine at the University of Florida, discovered a fluid that entered the bloodstream several times faster than water. He assigned the rights to Stokley-Van Camp, which marketed the fluid under the brand name "Gatorade."

Subsequently, both the U.S. government and the University of Florida asserted rights to Gatorade. The government based its rights on a grant from the Department of Health, Education and Welfare (as it was then known). HEW said the research fell within the scope of the "Work" sponsored by their grants. The University of Florida based its claim on the fact that Dr. Cade was an employee of the university subject to its policies.

An examination of the facts indicated that the definition of the "Work" under the grant was too vague to determine with any certainty that it covered this discovery. Further, the facts showed that Dr. Cade had requested funding from the University of Florida to work on a rapid thirst-quenching fluid, but was denied university sponsorship. Accordingly, Dr. Cade argued that his work on Gatorade was outside the scope of his responsibilities for the university.

Although this case was ultimately settled after it was fought for several years at a costly sum, this case illustrates the importance of the definition of the "Work" assigned to any contractor/consultant, the "responsibilities" assigned to a university employee or professor, and the effect that a university's denial of funds for a project has on the rights of the university to an invention arising from that project. Does the

university necessarily forfeit all rights to inventions arising from projects for which it denies support? Does such a denial take the project outside the scope of the professor's duties to the university?

Regrettably the law does not furnish a crystal clear answer—much depends on the circumstances unique to each case. There are several precautions, however, that a university may take to anticipate and, within reason, control the outcome of any dispute to title. These precautions will be discussed in the conclusion to this paper.

Before attempting to resolve the issues raised so far, it may be helpful to briefly review two other cases involving consultants, which illustrate what happens when an invention is fully "conceived" *before* the inventor becomes an employee/consultant and the right that may be asserted against an employee/consultant post-employment.

EFFECT OF CONCEPTION BEFORE EMPLOYMENT

Bailey v. Chattem, Inc.[7] illustrates what happens when a consultant conceives of an idea before working on a project but first reduces his idea to practice while working on that project. Here, Chattem Inc. produced a chemical substance, aluminum alkoxide, and was looking for ways to expand the market for its product. So Chattem hired Bailey as a consultant.

Bailey had previously worked on a problem involving a spray paint and he had discovered an idea for a chemical additive that would keep the paint in a spray gun thin enough such that the paint could be sprayed, but once sprayed would begin to thicken immediately: a property called "thixotropic."

Bailey found a way to add Chattem's aluminum alkoxide to a formulation for paint resin to make an effective thixotropic spray paint. Bailey then agreed to assign all his rights to Chattem for a royalty and he signed a "renewable" two-year

consultant agreement. Bailey later testified that it was his understanding that the consulting agreement would continue to be renewed.

Soon thereafter, problems developed. According to Chattem, the product was not marketable. But according to Bailey, Chattem never adequately promoted the product in the marketplace as a spray paint additive.

So Bailey sued Chattem for a breach of contract, claiming bad faith on the part of Chattem for not promoting and selling the alkoxide for spray paint and also for not retaining Bailey as a consultant during the life of the patent.

Chattem argued that the product did not sell so it had no further obligation to Bailey. Chattem also said that because the invention was first perfected or reduced to practice during the time Bailey worked for Chattem, it belonged to Chattem as a matter of law (as per *Standard Parts v. Peck*) so the royalty agreement gave Chattem nothing more than it had without an agreement, i.e., Bailey transferred nothing.

One central issue before the jury was whether Bailey had made the invention *before or after* he signed the consulting agreement. Although Bailey was able to produce evidence in the form of various writings on which his idea was based, he had no evidence demonstrating any *actual reduction* to practice until after he signed on as a consultant to Chattem. Chattem paid him during the time that he experimented with various formulations, including all his expenses for the facilities, equipment, and supplies. Of particular interest here was that the jury was also asked to decide whether Chattem owed its consultant, Bailey, an obligation to promote and commercialize the patented invention. That is, did the company, Chattem, have any implied obligation to commercialize the invention it acquired from Bailey? The jury found in favor of Bailey on all counts, awarding him $650,000 (an amount later reduced to the "present day" value of his future losses). In the eyes of the jury,

at least, Bailey made his invention *before* joining Chattem. The jury also said Chattem did have an implied obligation to commercialize the invention. In general, the law implies an obligation of good faith and fair dealing among parties in all contracts. The jury's decision in *Bailey v. Chattem* is consistent with that line of cases.

The important principle we learn from the *Bailey* case is that the law does *not* imply an obligation to assign an invention where the invention is fully conceived by an individual *prior* to entering into the employment or consulting relationship. Keep in mind that in the Bailey case, Bailey was able to demonstrate that he had the concept in the form of written documents, even though he had never reduced it to practice, *before* entering into his relationship with Chattem.

POST-EMPLOYMENT RIGHTS

One final case that may be helpful here is *Schlumberger Technology Corp. v. Frentrop*[8] because it applies to post-employment rights. In this case, Schlumberger had hired a consultant, Arthur Frentrop, and later sued to prevent him from consulting for a competitor, Gearhart Industries. Schlumberger provides services and equipment to help find oil and gas. The consultant, Frentrop, worked for Schlumberger on the development of a "neutron generator" to help detect oil and gas. Later, Gearhart Industries hired Frentrop as a consultant and Gearhart was also engaged in finding oil and gas. Schlumberger sued, seeking an injunction and Gearhart defended arguing that it had its own technology for finding oil and gas and did not hire Frentrop to take advantage of any of Schlumberger's secrets. Frentrop also argued that Schlumberger was trying to prevent him from earning a living as a consultant because his expertise was quite narrow and his livelihood depended on his ability to exploit his specialized knowledge. Schlumberger argued, on the other hand, that it had invested millions of dollars developing its technology and that Frentrop would necessarily use it or reveal it in the course of performing his

duties for Gearhart. The court granted Schlumberger a preliminary injunction because it found that there was a "substantial likelihood of disclosure" if Frentrop was to work for Gearhart in using this specific type of technology to find oil and gas. The court observed that Frentrop was not precluded from working for Gearhart outside that narrow area of technology.

That is a Solomon-like decision that, as a practical matter, may be very difficult to implement. In practice it is not always easy to draw an iron curtain between the consultant's new work for a client and the consultant's prior work if the application or objective of the consultant's new work is closely related to the prior work. By the same token, however, there is undeniable merit to the consultant's point of view that his or her expertise is limited to and based on a very narrow specialty and the consultant's value is greatly diminished outside that specialty.

ADDRESSING THE ISSUES

With the foregoing principles in mind, let's return to the problem that we posed at the outset of this talk. Your client is faced with an angry former client of its own, the manufacturer, for whom it had solved an engineering problem with the assistance of a consultant, whom your client had hired. Because the consultant's correspondence showed that he knew he was working on a project for the manufacturer, sponsored by the manufacturer, there is a strong ground for implying an equitable estoppel to prevent the consultant from now denying the manufacturer the right to use the invention. After all, in keeping with *Arkansas Power and Light*, the consultant was hired and paid to assist in that project, which he understood was for the benefit of the manufacturer. Although a shop-right is personal, here the shop-right was expressly created for the manufacturer and the inequity would apply to the manufacturer because directly or indirectly it paid for the use of the invention and for the services of the consultant.

But do the facts justify an implied assignment of title to the invention to your client? Because your client did not have any express agreement with the consultant, it would have to rely on the *Standard Parts Co. v. Peck* case and the *Teets v. Chromalloy* case, namely on the principle that it had engaged the consultant for a specific project and had paid him for that project. The consultant, however, may very well argue the principles of the *Aetna Standard* case and the *Liggett Group, Inc. v. Sunas* case that while he was hired to consult based on his expertise, he was *not expressly hired to invent* and that his employment was never specific enough to justify a determination that he was assigned specifically to make an invention or to perform work that necessarily resulted in the invention. It is also necessary to determine whether the consultant had any notes as to how early he conceived his invention, in keeping with the *Bailey* case.

More than likely, a court would follow the *University Patents* case and let a jury decide whether to imply an assignment of title from the consultant to your client. The process of discovery might help clarify when the consultant first worked on the invention, the scope of his responsibilities, and whether the invention was a direct outgrowth of the consultant's assigned responsibilities on the project.

A unifying principle is whether the invention has any generic application outside the scope of the project. An invention that has no use outside the scope of the project was created at least inferentially within the scope of employment on that project. A new design, for example, that applies only to a new apparatus created in the course of a specific project suggests that the design is a direct result of the consultant's assignment to the project. Should that same design, however, have general application outside the project, then this inference would favor ownership by the inventor, subject to a possible shop-right to the employer.

For the university to assert a claim, it would have to establish an agreement, or circumstances implying an agreement, that any

inventions made by a professor, while an active faculty member, would be owned by the university, regardless of sponsorship. In the absence of establishing such an agreement, the university may still acquire some residual benefit. For example, if university facilities were used by the consultant, then, as in *Arkansas Power & Light*, the university may have a shop-right. Although a shop-right is personal and not transferable, still the university through its faculty would acquire a right of "use" not otherwise permitted under the patent laws. True, this may or may not mean much, depending on the nature of the discovery and whether it lends itself to being used as a research tool or stepping stone to further research. There is no substitute, ultimately, for an agreement with and signed by the faculty member.

CONCLUSION

A.) Facing the Danger

The facts of the case as presented here are very real and demonstrate the dangers in the determination of ownership rights, both with consultants and with employees in the absence of a specific written agreement. The mere existence of a company policy or a university policy is no guarantee that it will necessarily control the issue of ownership of rights to an invention.

B.) The Best Approach

For that reason, it is strongly recommended that respective rights to any possible inventions in an employment or consulting agreement be defined in a written agreement signed by the inventor employee/consultant or faculty member. Several key provisions for such an agreement are listed as an Attachment. Beware of "form" agreements because they may not fit the needs of every employer or university or apply to every situation. The best agreements are written with the specific needs of the particular employer/university in mind to address

the immediate concerns and special issues affecting that employer/university.

C.) The Key to Avoiding Problems

While the departments within major universities are sometimes compared with fiefdoms, with every tenured professor a feudal lord, the key to their cooperation is education and communication. Many faculty members who disdain to obey university policies they consider arbitrary, become cooperative once they understand the benefit to themselves, as well as the university. Accordingly, any mass distribution of policies, or revisions to policies, is likely to be ignored. No matter how difficult it may be, tenured university professors must be reached individually.

Certainly at the time of hiring, faculty members can be informed of and asked to sign agreements acknowledging the rights of the university to an invention made by the faculty member, whether it arose from an authorized university sponsored project or not. That agreement should clearly spell out the obligation to inform an appropriate office of the university of any and all agreements or understandings, whether oral or written, relating to the sponsorship/funding of any work or projects including any consulting arrangements. If nothing else, compliance with that notification permits the university to review and prevent multiple transfers of rights to the same invention or technology.

Most universities share royalties or monies received from transferring rights to inventions with the faculty members responsible for the invention. A sharing arrangement that provides funds for continued work by faculty members as well as some direct payment to the faculty member is likely to provide further incentive for faculty cooperation.

At departmental or other meetings, as appropriate, a university representative should explain the key provisions of the

university policy and take a list of attendees. The latter may help prevent the defense of ignorance of university policy used by Dr. Kligman and others.

At each opportunity, faculty members should be asked to execute an acknowledgement of the then-current university policy. For example, in connection with a pay raise or promotion or the filing of a patent application or some similar event benefitting the faculty member, the opportunity to obtain a written acknowledgement of current university policy should not be forfeited.

Early disclosure of inventions to the university by a faculty member is important to prevent the loss of patent rights, particularly in most foreign countries where publication precludes subsequent patent rights. The United States is the only major industrial country with a twelve-month grace period from disclosure to filing. Once more, education of faculty members as to the need for time to prepare and file a patent application prior to submission for publication is essential to gain cooperation.

The clarity of the key terms spelling out the scope of the work to be undertaken, the responsibilities assumed, disclosure requirements, and ownership rights governing the relationship will prevent misunderstandings and lawsuits, provided, of course, that the employee, consultant, or faculty member signed an agreement or an acknowledgement to be governed by the policy of the university. Otherwise, the opportunity remains for the individual to plead that he or she did not agree to the terms involved (no matter how clearly defined).

In the realm of a university, the need for strong lines of communication is proportional to the size of the university. Reliance on the mere distribution of policy statements and manuals is foolhardy. Continued communication to ensure recognition of at least the key provisions of university policies,

to prevent ignorance and indifference, is essential to the ultimate acceptance and enforceability of university policy.

Finally, the issue of ownership should be carefully examined prior to signing an agreement for the license or rights to technology. The failure to inquire into the circumstances under which the invention was made and the rights involved may constitute a basis for malpractice for lack of due diligence.

ATTACHMENT

Key Provisions in Employee and Consulting Agreements

A. The Parties

B. The Scope of the Work for which the Consultant/Professor is Hired or Assigned, by Contract or Otherwise

C. Reporting Procedure and Location of Work

D. Duration of the Agreement

E. Compensation

F. Consultant/Professor Obligations and Duties toward Employer/University

1. Confidentiality and Trade Secrets

2. Disclosure of Ideas and Inventions (Patentable or Not)

3. Disclosure of all contracts, agreements, or understandings, whether oral or written, for the sponsorship or funding of research projects, consulting work, and/or any Work that may give rise to one or more inventions, whether patentable or not

G. Ownership of Rights to Inventions and Ideas (Patentable or Not)

H. Post-Employment Use of Know-How, Technology, and Inventions

NOTES

1. 264 U.S. 52 (1924).
2. 437 S.E.2d 674, 30 U.S.P.Q.2d 1678.
3. 995 F.2d 1576.
4. 20 U.S.P.Q.2d 1401.
5. 228 U.S.P.Q. 292.
6. 83 F.3d 403 (Fed. Cir. 1996).
7. 684 F.2d 386 (6th Cir. 1982).
8. 215 U.S.P.Q. 1072 (D. Conn. 1981).

Implications of Joint Ownership of Patents

Kathleen R. Terry*

As companies downsize their research and development efforts in the drive toward greater efficiency in today's tough commercial world, they increasingly turn to universities and research institutions to help fill the voracious product pipeline. Through collaborative research and joint development of inventions licensed from universities, scientific teams from both partners often work jointly to make patentable discoveries. Ownership is seldom a "sticking point" in the negotiations leading to the research contract. The standard, equitable agreement is that inventions made solely by the employees of each party will be owned by that party. Inventions made jointly by employees of both parties will be jointly owned. Therein lies a problem.

1. EFFECTS OF JOINT OWNERSHIP

> *35 U.S.C. §116 — When an invention is made by two or more persons jointly, they shall apply for a patent jointly and each make the required oath....Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make*

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the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the application.

35 U.S.C. §262 — In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, sell, or offer to sell the patented invention within the United States, or import the patented invention into the United States without the consent of and without accounting to the other owners.

A. Substantive Effects

Two recent cases may have put a chill on a corporation's willingness to agree to joint ownership and may make technology transfer managers think carefully before doing so.

In the first case, two scientists jointly patented a method of combining two classes of drugs for treating prostate cancer. One assigned his joint ownership to Roussel-UCLAF SA; the other to Schering Corporation. Schering moved ahead with development, but Roussel did not. Zeneca, Inc. was developing a similar treatment and subsequently began to market its own combination. Schering filed suit against Zeneca. As litigation loomed, Zeneca took a non-exclusive license to the patent from Roussel. The trial court dismissed the suit, holding that as licensee of a co-owner, Zeneca was not an infringer. The Federal Circuit agreed. (*Schering Corp. et al. v. Roussel UCLAF SA,* 41 USPQ2d 1359 (CA Fed. Cir. 1997).)

In the second case, a doctor licensed to Ethicon a patent that named him as a sole inventor. During the development of the invention he hired a young man who had some experience with electronics to assist him with one embodiment of the trocar. The assistant was not

named as an inventor. The electronic model read on two of the fifty-five claims of the issued patent. Some time later, Ethicon sued United States Surgical for infringement of the patent. United States Surgical located the young man, added him as inventor to the patent (see Endnote), and took a license from him as joint owner. Citing *Schering*, the trial court dismissed the case and the Federal Circuit affirmed the decision. (*Ethicon, Inc. v. United States Surgical Company* 45 USPQ2d 1545 (Fed. Cir. 1998).)

These recent cases confirm the rule that has been the law since *Drake v. Hall*, 220 F 905 (7th Cir. 1914), and *Willingham v. Lawton*, 555 F2d 1340 (6th Cir. 1977). The *Willingham* court stated, "The nature of a patent is such that co-owners are at the mercy of each other. A co-owner of a patent can even grant a license to a third party without the consent of the other owners and neither co-owner-licensor nor the third party licensee is liable to the other owners."

Prior to 1984, an inventor had to contribute to each and every claim of the patent. In a strong dissent in *Ethicon*, Judge Newman expressed her opinion that with abandonment of the "all claims" rule, ownership should be separate from inventorship and that a joint inventor should have rights only to the claims to which he contributed creative concept. However, barring Congressional action, the old rule endures.

B. Procedural Effects

University technology managers are well aware of time-sensitive procedures in filing and prosecuting patents both in the United States and in foreign countries, and also how difficult it may be to get the proper university signatory to sign papers. Certain documents require the signature of all owners. One example is notification to

the United States Patent and Trademark Office ("PTO") of the attorney chosen to represent all parties. The *Manual of Patent Examining Procedures* §402.10 specifies that papers giving or revoking a power of attorney in an application require the signature of all applicants or owners of the application. Although applications can be filed informally, the executed power of attorney must be submitted to the PTO within six months of receiving a Notice of Missing Parts. During the course of prosecution, if the joint owners become dissatisfied with the designated attorney, revocation of the power of attorney and appointment of a new attorney must be done quickly. If the documents must be sent to multiple owners, some of whom are slow to sign, the application could go abandoned because the six-month limit was exceeded. Revival of an abandoned application is both time-consuming and expensive.

A worse situation arises when fewer than all the owners have appointed the same attorney. In such a case, all those holding interest will be required to sign each and every paper submitted to the PTO, but only the first attorney of record will receive communications from the PTO.

Title 35 of the United States Code, the patent statute, sets a "statutory period" of six months for response to correspondence with the PTO during patent prosecution. This statutory period cannot be extended but is often shortened by the PTO to two or three months (without paying a fee), although applicants can "buy" extra months up to the six-month limit for a fee, which can be as high as $1,510 for a four-month extension. More important than the additional cost, if time is lost because of the time needed to secure all signatures from two or more joint owners, patent term is lost under the twenty-years-from-filing term.

Under the Federal Rules of Civil Procedure 19 (a), a suit may not go forward unless certain "indispensable parties" can be brought into the suit. Joint owners are generally considered to be indispensable parties in filing suit against infringers and may be joined as involuntary plaintiffs. Roussel was joined as an involuntary plaintiff in the lower court in the *Schering* case. If a joint owner is unwilling or unable to be joined in the suit because of other obligations or cost, the suit is dismissed, which often leads to a new lawsuit against the uncooperative owner, as happened to Roussel.

It is even possible, although not likely, that a joint owner might be pulled into a case as a defendant and be unable to refuse such joinder. In either situation, whether plaintiff or defendant, one would not dare put forth less than the best effort. The costs of losing can be astronomical and the mere cost of appearance in an inconvenient or unfriendly forum can be very high.

2. AVOID OR CURE JOINT OWNERSHIP PROBLEMS

A. Carve Out the Contributions into Separate Patent Applications

Even when an invention has been made under collaborative research, it may be possible to separate the individual contributions made by employees of the parties into separate patent applications. Whenever that is the case, problems may be avoided by this technique.

However, in order to avoid the problems of setting forth the best mode to make and use the invention and the obviousness/anticipation effect one may have on the other, it is wise to file the entire invention in one application. Both sets of claims can be filed, and the PTO may issue a restriction requirement on the grounds that the application discloses more than one invention.

If restriction is not forthcoming, then one set of claims can be canceled and filed in a divisional application. (See Endnote for a clarification of inventorship and naming inventors.)

An example may be useful to translate the above "patentese" into English (or at least into "chemistrese"). Suppose a university inventor invents a new compound and a company scientist invents a method to make one enantiomorph of the compound. They are working together and each is aware of the other's work. 35 U.S.C. §112 requires the inventor to set forth in the specification *how to make and use* the invention and also the *best mode known to the inventor at the time of filing* of the patent application. The chiral compound has twice the activity of the racemic compound and fewer side effects, and therefore making the chiral compound is the best mode of making. The company scientist knows how to make it but has no idea how to use it except through communication with the university scientist. Neither can really satisfy §112 requirements without access to the data of the other and therefore, the invention should be filed in one patent application. Following restriction and the separation into two applications, the company scientist is properly named as inventor of the process of making the invention and the university scientist is properly named as inventor of the process of using the invention.

B. Assign the Inventions to One Party in the Collaboration Agreement

35 U.S.C. §103 (c) Subject matter developed by another person, which qualifies as prior art only under subsection (f) ["invented by another"] or (g) [interference] of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at

> *the time the invention was made, owned by the same person or subject to an obligation to assign to the same person.*

Besides avoiding the procedural and substantive effects of joint ownership, agreeing to assign all joint inventions to one of the parties before the research begins will avoid internal collision. In the case of joint inventors each assigning to his or her own employer, it is possible that the subject matter developed by an employee of one party, not incorporated in the patent application and not communicated to the other inventors, and therefore *not* part of the joint invention, may rise up later to destroy the patent. The unnamed one is "another" for §102(f) purposes and if his or her knowledge can anticipate or make obvious the invention, then the resulting patent can be invalidated.

Many collaboration contracts state that each party owns inventions created solely by its own employees, even inventions arising out of the collaborative research. Separately owned patent applications may be related closely enough to trigger an interference proceeding under §102(g). The third paragraph of §103 was initially promulgated to overrule a case in which a large corporation, with several separate research facilities, was forced into an interference with itself, but the advantages of an obligation to assign to the same person can be applied to any contractual agreement.

Recently, very secret prior art has been found that defeats patentability. In *Oddzon Products v. Just Toys, Inc.* 43 USPQ2d 1641 (Fed. Cir. 1997), a patent was found to be obvious over designs shown to the inventor by an unrelated person, even though the prior art designs were not publicly known. Like *Ethicon, Oddzon* cautions us never to underestimate the ingenuity of a lawsuit defendant.

Which party should take title? There may not be a choice. Some universities, such as State University of New York, are required by law to take title to inventions made with the use of university facilities. Any inventions "conceived or first reduced to practice"--a big umbrella—under U.S. government funding must be assigned to the university. The corporate partner, especially if it is a small, start-up company, may be under stockholder or investor pressure to retain title. Either party may be reluctant to "give away its birthright." However, assignments are not necessarily forever. Title can be transferred in an agreement that specifies that title will be reassigned to the other party in certain situations, such as failure of the licensee to exercise due diligence in commercialization.

If it is not possible to place title to joint inventions in the U.S. patent application to one party, it may be worthwhile to attempt permission to assign foreign rights, preferably to the corporate partner. While time-sensitivity and processing of papers are onerous enough in the United States, the problem multiplies exponentially for foreign filings. For a number of countries, the process may involve: notarized signature at the university followed by a statement from the County Clerk that the notary who witnessed the signature was truly a notary followed by a statement from the State Secretary of State that the person signing for the university had the power to do so followed by a statement from that country's ambassador or consul that the person claiming to be the secretary of state really was the secretary of state. If the invention is a pharmaceutical invention filed worldwide, tracking the paperwork will require a significant effort on the part of the technology transfer office.

C. Joint Ownership Cannot Always Be Avoided

If two or more joint inventors are bound by inflexible rules to assign each to his or her own employer, joint ownership cannot be avoided. Nor can joint inventorship always be predicted and "fixed" ahead of time. University faculty continually communicate and informally collaborate with one another and if a joint invention arises, it will by operation of law be first owned by the inventors. "Whoever invents or discovers [an invention]... may obtain a patent therefor..." 35 U.S.C. §101. The patent must be applied for in the name of the inventor.

"Solving" the ownership problem by "forgetting" to add the joint inventor who has a duty to assign to a different employer is tempting, but highly dangerous (and unethical). Misjoinder (naming the wrong inventor) or nonjoinder (omitting an inventor) both result in invalidity of the patent. An inventor cannot be heard to speak against the validity of the patent, but a nonjoined inventor, who knows all of the details of the invention process, can testify against the patent and has been called "an expert witness for the other side." As *Ethicon* shows, the nonjoined inventor can be added to the patent later and then becomes "licensor to the biggest competitor." (See Endnote for explanation.)

D. Contractual Terms Can Alleviate Problems

After initially vesting in the inventor, "[P]atents shall have the attributes of personal property....[and] shall be assignable in law by an instrument in writing..." 35 U.S.C. §261. A carefully drawn agreement that lays out exactly how the joint owners intend to utilize the patent can eliminate the potential legal tangles arising from joint patents. One owner can exclusively license the other for all fields of use, or the owners may divide up fields of use in which each has exclusivity. Whatever the

agreement, it should be carefully thought out and drafted to reflect the intent of the parties.

The ownership agreement in *Schering* attempted to cover all the bases. The parties agreed to notify each other of any infringement of the patent and "render all reasonable assistance" to the party taking action against infringement. Schering based its case on this clause, saying that it invalidated the license to Zeneca. The court did not agree.

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In spite of the problems that can arise from joint invention and joint ownership, there are advantages to both participants (as well as burdens). First, many collaborations do not give rise to joint inventions. Second, combining creative capacities increases the value of the technology and can have a stimulating or synergistic effect that leverages the research investment of both parties. Finally, the corporation contacts may lead to career opportunities for the university researcher's graduate students.

My thanks to Paul Morgan of Xerox Corporation. His article in the December 1997 issue of the "AUTM Newsletter" on the perils of joint ownership of patents is the basis of this paper, and he has contributed many thoughtful comments. My thanks also to Dr. Rochelle K. Seide, Baker & Botts, L.L.P. and Dr. Warren D. Woessner, Schwegman, Lundberg, Woessner & Kluth, P.A. Their recent papers on §112 and inventorship published in "Advanced Biotechnology/Chemical Patent Practice Seminar," American Intellectual Property Law Association, 1998, formed the basis of the Endnote on inventorship.

ENDNOTE

Who is the Inventor?

Defining inventorship has always been a difficult question to resolve. Invention is comprised of two distinct acts: conception and reduction to practice. One hundred years ago the D.C. Circuit Court of Appeals articulated the basic rule. Conception, which is the touchstone of invention, occurs when the inventor or inventors have formed in their minds a permanent and concrete idea of an invention as it is to be applied in practice. (*Mergenthaler v. Scudder*, 11 App.D.C. 264 (D.C. Cir. 1897).) If the idea is *permanent, concrete, and complete,* the invention is made and the person or persons forming the idea are the inventors. Subsequent reduction to practice does not confer inventorship if the one carrying out the reduction is a "mere pair of hands" or "mechanic" working under the direction of the inventors.

Real life is never so simple. One hundred years after *Mergenthaler*, his linotype is not used and the teachings of his case are still unclear. When did the idea become permanent and concrete? Most research involves tinkerings and changes right until the filing of the patent application. Are the changes substantial enough to constitute a new conception? As new technology is defined and clarified, ideas of inventorship change. In the biotechnology area, it has been held that conception is incomplete until actual reduction to practice occurs, because nothing short of a demonstration of a means of preparing the compound or preparation could enable a practitioner of ordinary skill in the art to prepare the conceived material ("simultaneous conception and reduction to practice"). (*Amgen, Inc. v. Chugai Pharmaceutical Co. Ltd.* 18 USPQ2d 1016 (Fed. Cir. 1991).) In *Fiers v. Sugano* 25 USPQ2d.1601 (Fed. Cir. 1993), the court concluded that an invention of a DNA sequence has not been achieved until the sequence has been determined. Both of these decisions may trigger a reconsideration of inventorship. To finish confusing the reader,

I pose this question: who is the inventor of a new drug made by the techniques of combinatorial chemistry? The computer programmer? The professor who "expressed a wish for a result?" The bench scientist who followed the directions of the computer printout? I don't know either.

Some things are clear. Inventorship is not a status honor. The department head or project manager should not be named as inventors if they did not contribute inventive concept to at least one claim of the patent. The pair of hands should not be named. The janitor in *Good Will Hunting* might be an inventor if, in kibitzing and watching some researchers struggle to perfect a process, remarks, "You know, if you close that valve and open that one for twenty seconds, the thing will work." The contributions of one of a research team might have been published for more than one year, and is therefore time-barred from being claimed in a patent.

Inventorship cannot be finally determined until claims are allowed. At that point, some inventors may need to be dropped because claims covering their contributions were not allowed. At any time that it is discovered that an error in inventorship has been made, inventorship can be corrected, provided that the error was made without deceptive intent. While the application is still in prosecution, inventorship is simply corrected by amendment. After the patent is issued, inventorship can be corrected by petition to the PTO or by order of a District Court. (37 C.F.R. §1.48(a).)

This brief note suffices only to give a glimpse of determination of inventorship. A full explanation is beyond the scope of this article.

What is a "University" for "Small Entity" Purposes in Canadian Patent Law?

Sheldon Burshtein*

As in the United States, Canadian patent law permits "small entities" to pay reduced fees for certain services offered by the Patent Office. The new Canadian *Patent Rules*[1] that took effect on October 1, 1996, have redefined the term "small entity" to include a "university" or, in the French version, "université."[2] A "small entity" is defined differently in Canada than in the United States. In Canada, a small entity means "an entity that employs 50 or fewer employees or that is a university, but does not include an entity that:

(a) has transferred or licensed, or is under a contractual or other legal obligation to transfer or license, any right in the invention to an entity, other than a university, that employs more than 50 employees; or

(b) has transferred or licensed, or is under a contractual or other legal obligation to transfer or license, any right in the invention to an entity that employs 50 or fewer employees or that is a university, and has knowledge of any subsequent

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> transfer or license of, or any subsisting contractual or other legal obligation to transfer or license, any right in the invention to an entity, other than a university that employs more than 50 employees."

The Canadian Patent Office[3] and Canadian patent practitioners seem to be in some doubt as to what constitutes a "university." More particularly, issues arise as to whether a legal entity that is affiliated with a university, such as a related organization set up to exploit research, qualifies as a "university" for the purposes of small entity status. This article attempts to define the term "university" for the purposes of the *Patent Rules.*

1. Dictionary Definitions

Neither the *Patent Rules* nor the *Patent Act*[4] provides a definition of the term. It is always helpful to consider dictionary definitions as a starting point. Webster's defines "university" as follows:

> 1 a *archaic:* a body of persons gathered at a particular place for the disseminating and assimilating of knowledge in advanced fields of study; b: an institution of higher learning providing facilities for teaching and research and authorized to grant academic degrees: as (1): an institution in the British Commonwealth authorized to hold examinations and confer degrees and usu. consisting of several affiliated or associated colleges; (2): a continental European institution concentrating on or exclusively concerned with advanced or professional study; (3): an institution made up of an undergraduate division which confers bachelor's degrees and a graduate division which comprises a graduate school and professional schools each of which may confer master's degrees and doctorates; c: the physical plant of a university.[5]

Funk & Wagnalls defines the term as:

> 1. an institution for higher instruction that includes one or more schools or colleges for graduate or professional study and grants master's and doctor's degrees. In the United States, a university usually includes an undergraduate division that grants a bachelor's degree; 2. the faculty and students of the university; 3. the buildings and grounds of a university; 4. a university team or crew.[6]

A French language dictionary defines "université" as:

> 1. Chacune des institutions ecclésiastiques d'enseignement secondaire et supérieur, nées de la fusion des écoles cathédrales; 2. corps des maîtres de l'enseignement public des divers degrés; établissement d'enseignement supérieur constitué par un ensemble d'unités de formation et de recherche, d'instituts, de centres et de laboratoires de recherche; association donnant l'instruction aux adultes des milieux populaires.[7]

2. Common Law

However, one must consider whether the term "university" has a specific meaning in law. In at least one case, the Federal Court has said the common law is available to interpret the *Patent Act*.[8] In these circumstances, it is appropriate to look at how the common law has defined the term "university." For this purpose, we are not without precedent. It is nevertheless not easy to determine exactly what qualifies as a "university"; it has been said that "the word 'university' is not a word of art, and, although for the most part one can identify a university when one sees it, it is, perhaps, not easy to define it in precise and accurate language."[9]

The terms "school," "junior college," "college," and "university" all convey similar ideas, indicating an institution of learning consisting of trustees, teachers, and scholars, engaged in imparting knowledge to resident students and possessing the rights to confer diplomas or degrees."[10] Many institutions, not formally entitled "universities," may in certain ways be said to give a university education and have standards and teaching of a quality that is to be found in a university. However, no matter how closely such institutions approximate the aims, character, activities, and merits of a university, they may not be universities, for the fact that an educational institution possesses all or most of the essential qualities of a university does not necessarily mean that it is a university.[11]

It has been judicially acknowledged in the United States that, although a university ordinarily implies a higher calibre of education than a college, it is difficult to make the distinction.[12] What then is a "university"? A university is an institution in which the education imparted is universal, embracing many branches, such as the arts, sciences, and all manner of learning.[13] Hence, it has been said that a true university demands the representation of all faculties.[14] More importantly, the chief distinguishing characteristic between a university and other institutions of learning is the power and authority possessed by a university to grant titles and degrees such as Bachelor of Arts, Master of Science, or Doctor of Philosophy, by which it is certified that the holders have obtained some definite proficiency.[15] Therefore, it is submitted that, unless an institution instructs and examines in what some consider the more important branches of learning and possesses the power by statute or charter to grant degrees, it would not qualify as a "university."

3. *City of London* Case

The leading Canadian case on the meaning of the word "university" is the Ontario Court of Appeal decision in *Re: City of London and Ursuline Religious of The Diocese of London.*[16] Ursula College was affiliated with the University of Western Ontario[17] and entitled to provide courses leading to a degree that could only be conferred by the University of Western Ontario.[18] The Ontario *Assessment Act*[19] provided an exemption from assessment for real property where such property is "*bona fide* used in conjunction with and for the purposes of a university."[20] It was held on appeal by way of stated case that the college was not itself a university and that the property in question was not used for the purposes of the university.[21]

Holding that Ursula College was not a "university," the court followed the British case of *St. David's College, Lampeter v. Ministry of Education.*[22] That case involved a declaration sought by the college that it was a university for the purposes of

qualification for university awards by the Minister of Education.[23] St. David's was founded in 1822 and incorporated by royal charter in 1829. It was further regulated by subsequent royal charters. While originally it was exclusively a theological institution, it later provided instruction in languages, mathematics, and sciences. Its students numbered about 170, of whom approximately four-fifths intended to take holy orders. Admission to the college was not limited to persons from any locality. In the royal charters, the college had been granted the right to confer only bachelors degrees in arts and divinity.[24]

In deciding that the college was not a "university," Mr. Justice Vaisey made the statement quoted above.[25] He then went on as follows:[26]

> Counsel for the plaintiffs has enumerated what he regards as the essential qualities which justify an institution being described as a university, and I do not think that there is much doubt that essentially, with exceptions which I will mention, St. David's possesses those qualifications. He said, in the first place, that it must be incorporated by the highest authority, i.e., by the sovereign power, succeeding, no doubt, to the Papal privilege which was exercised in Christendom in the middle ages by the proper, and indeed, only body which could incorporate and give authority to a great teaching institution. There is no doubt that St. David's College was incorporated and reincorporated and that its incorporation was confirmed and strengthened by acts of the sovereign power, that is to say, by royal charter.
>
> Secondly, it is suggested that to be a university, an institution must be open to receive students from any part of the world. There, again, there is no suggestion that there is any bar to students from any locality at St. David's College. It is said further that there must be a plurality of masters, i.e., that there cannot be a university with only one teacher. It is clear from the charters that those who teach in this college are numerous. Again, it was suggested that a university, to be such, must be an institution in which at least one of the higher faculties is taught, those higher faculties being, of course, theology - the queen of sciences - law or philosophy, which in some definitions are regarded as identical, and, thirdly, medicine. Then it is said that there cannot be a university without residents either in its own buildings or near at hand. It is said that residence

is a necessary qualification. I have left until last what is stated to be the most obvious and most essential quality of a university, that is, that it must have power to grant its own degrees. Here we find the very curious situation that the royal prerogative of granting degrees in the various faculties and branches of knowledge has been granted to this particular institution subject to a very strict limitation. It is only entitled to grant the degrees of bachelor of arts and bachelor of divinity. It has not of its own essential power any right to grant degrees, but to that limited extent the royal privilege has been acceded to it by royal concession.

That being the position, I have no doubt that St. David's College possesses (I will come back to the question of degrees) most of the necessary ingredients that go to make a foundation or institution a university, but, if the word "university" is not one of art, I have to try to see what it means, regard being had to those particular qualities which I have enumerated. I have to see whether or not, in accordance with the ordinary language of mankind, this small college, doing admirable work, is properly to be described as and ought to be regarded as a university. I think that it is very difficult, when you are dealing with a word of general import like this, to lay down the precise criteria, but I ask myself what the ordinary man would say if he were asked whether this college was a university. I am not referring to the man in the street - a man who, perhaps, has had no university education or no experience of what a university is - but to the ordinary man who does know what a university is or who has received his education at a university. I cannot bring myself to believe that such a man would say that St. David's College, Lampeter, was a university. It does not, I think, follow that, if it possesses all or most of the qualities of a university, it necessarily follows that it is a university. I am inclined to think that the onus must lie on this institution, which has never been called a university in any of its charters. It is true it is included among the universities in, for instance, such a well known reference book as *Crockford's Clerical Directory* and it may for some purposes count as a university or be considered as equivalent to a university, or to use another phrase, to rank as a university or to provide instruction of university standard. I cannot bring myself to think that that is enough. I cannot help feeling that this extraordinarily limited power of granting degrees, which has throughout been regarded during the arguments as being really the test for the solution of this problem, is an indication that this institution falls short of a university properly so called. It was suggested to me that weight must be given to the fact that, in the charters on which its existence depends on by which it

> was founded, though there are possible slight indications the other way, care is taken not to call this institution a university. It was never incorporated as a university, and although the word may not have any technical significance and one can imagine a case in which a teaching institution is given such plenary powers of instruction and so forth as would lead irresistibly to the conclusion that the Crown intended to make it a university, I do not think that this is such an institution. Although it must not be supposed for one moment to think that a university has to be judged by its size or the number of its pupils or by the range of instruction which it gives, still, size is a matter of some consideration. I cannot believe that this one single college, this one single educational establishment, with all its merits and the good work which it does and all the advantages which it gives to those who resort to it for instruction, in any ordinary sense of the word could properly be described as a university.
>
> ... It has never called itself a university and, although included with the universities in certain books of reference, I have had no evidence to show that anybody has ever referred to it as a university. It may in certain ways be said to give a university education, that its standards are those of a university, and that its teaching is of the quality which is to be found in a university, but there still remains the gap to be bridged, the doubt whether, however closely it approximates its aims, character, activities, and merits to a university, this college can properly be described as a university. Judging the matter both on broad principles and on the narrow principles of its limited powers and the absence of any express intention of making it a university by the sovereign power, I think that the plaintiffs have not discharged the onus of satisfying me that the college ought to be called and to be considered, in accordance with the proper meaning of the English language, a university.

It may be the case that the Canadian concept of a university is not necessarily the same, Canadian institutions having more humble origins than the traditional universities in England.

In the *Ursula College* case,[27] Schroeder, J.A., speaking for the court, reviewed several definitions of the term:[28]

> In Wharton's Law Lexicon, 14th ed., p. 1026, "University" is defined as "an association of learners, and of teachers and examiners of the learners, upon whose report the association grants titles called

'degrees' (such as 'Master of Arts', 'Doctor of Divinity'), showing that the holders have attained some definite proficiency."

In Murray's New English Dictionary, "university" is defined as "the whole body of teachers and scholars engaged, at a particular place, in giving and receiving instruction in the higher branches of learning; such persons associated together as a society or corporate body, with a definite organization and acknowledged powers and privileges (especially that of conferring degrees), and forming an institution for the promotion of education in the higher or more important branches of learning."

In 13 Hals., 3rd ed., p. 707, para. 1441, it is said that "The word 'university' is not a word of art . . . The essential feature of a university seems to be that it was incorporated as such by the sovereign power." It is stated that "other attributes of a university appear to be the admission of students from all parts of the world, a plurality of masters, the teaching of one at least of the higher faculties, namely theology, law, or philosophy, which in some definitions are regarded as identical, and medicine, provision for residence, and the right to confer degrees, but possession of these attributes will not make an institution a university in the absence of any express intention of the sovereign power to make it one."

Then, after referring to the *St David's College* case,[29] Schroeder, J.A., said:[30]

The chief distinguishing characteristic between a university and other institutions of learning is the power and authority possessed by an institution of learning to grant titles or degrees such as Bachelor of Arts, Master of Arts, or Doctor of Divinity, by which it is certified that the holders have attained some definite proficiency. It is not pretended that the respondent is invested with such power or authority . . . Unless an educational institution for instruction and examination in the more important branches of learning possessed the power by charter or statute to grant degrees, it did not qualify as a university. When measured by that standard the respondent clearly does not possess the status of a university.

4. Subsequent Decisions

A few other Canadian cases are also of interest. In *Vanek* v. *Governors of the University of Alberta*,[31] the court considered

whether a decision of a university committee to deny tenure to a professor could be overturned by the courts if the committee failed to provide procedural fairness to the professor. In the course of its decision, the court said that the University of Alberta in its functions has two aspects. One is the temporal administration of the institution. The other is its eleemosynary function as a corporation for the promotion of learning and the support of persons engaged in education.[32] The judgment adopted a passage from an article of Professor Ouelette,[33] in which he suggested that a university can be defined as "a community of professors and students."

In *Riddle* v. *University of Victoria*,[34] the court was asked to determine the applicability of a limitation period relating to acts done in the execution of a public duty. At issue was whether the University of Victoria was executing its public duty when it hired a teacher and signed an employment contract. The teacher was suing for breach of that contract. In its decision, the court found the following argument of the university "convincing":[35]

> [Counsel for the university] points to the definition of "university" in the New English Dictionary, cited in *re City of London and Ursuline Villages of Diocese of London* [*supra*] and says that a university is "the whole body of teachers and scholars" or, as in the *Vanek* case, [*supra*] "a community of professors and students" ... and points out that ... the essential functions of a university are the pursuit of knowledge and understanding through research and training.

It is interesting to note that, while the court suggested that "research" is essential, the research is related to training as part of the "pursuit of knowledge and understanding." Query whether the commercial application of that research, either directly or through licensing, is essential.

The most recent case to deal with the definition of a "university" is *City University* v. *Canada*.[36] City University provided courses and presented baccalaureate and master degrees in a number of disciplines. The courses were provided

in Vancouver, British Columbia and students wrote examinations prepared by, and received degrees from, City University in Bellevue, Washington. City University had been accredited in the United States under appropriate standards and was authorized by the legislation of the State of Washington to grant degrees. The Tax Court of Canada was asked to determine whether City University was a "university" for the purpose of the *Excise Tax Act*.[37] At issue was whether City University should be liable for collecting and remitting the federal goods and services tax in connection with its services. Subsection 123(1) of the *Excise Tax Act* defined "university" as "a recognized degree-granting institution and an organization or that part of an organization that operates a college affiliated with such an institution or that operates a research body of such an institution."

The court held that City University was a "recognized degree-granting institution" despite the fact that it was not accredited by a Canadian authority. Thus, City University was not required to collect and remit GST. Of interest is the statement in the decision that "there is nothing in the definition of 'university' which requires the institution to be Canadian, to be recognized in Canada only, or to grant Canadian degrees."[38] While this case turned on the interpretation of the statutory definition of "university," it is of note that the definition in the *Excise Tax Act* focuses on the granting of degrees. Yet the definition makes reference to an organization that operates a research body of such an institution. Again, the question of whether such research is to be commercially applied is not addressed. In any event, the definition in the *Excise Tax Act* is directed to the limited purposes of that statute.

5. Power to Grant Degrees

It seems that, while one may look at all the circumstances, including internationality of students,[39] diversity of instructors,[40] multiple disciplines of higher learning,[41] resident students,[42] and size,[43] whether an institution has been incorporated by the

sovereign power[44] and referred to as a "university" in its incorporating document[45] will be more relevant. However, the key criterion appears to be the power and authority of the institution to grant titles and degrees by which it is certified that the holders have attained some proficiency.[46]

The ability to grant degrees may be strictly prescribed. For example, in Ontario, the *Degree Granting Act*[47] limits the entities who may grant degrees[48] and use the term "university."[49] Universities are generally legal corporations owing their existence to charter or statute. In Canada, it is normally the latter. Some provinces have a single statute governing the incorporation of all universities within the province,[50] while, in others, each individual university is incorporated by a special act.[51] In the United Kingdom universities have traditionally been incorporated by Royal Charter issued by virtue of the Royal Prerogative.[52] Of the major Canadian universities, McGill University[53] was so incorporated and is therefore a chartered, as opposed to a statutory, corporation. Queen's University was originally incorporated by Royal Charter,[54] but has since been made the subject of federal legislation.[55]

6. Conclusion

In conclusion, it appears that the most important criterion in qualifying an institution as a university is its ability to grant degrees. The university need not be located or accredited in Canada.[56] However, many institutions affiliated with universities do not themselves qualify as universities.[57] This would be particularly true of related entities that are set up expressly for the purpose of commercializing research conducted at a university but which do not grant degrees, such as an entity whose shares are owned by a university. It would be possible to include in the *Patent Rules* a definition of "university" along the lines of that in the *Excise Tax Act* if it were desired to broaden the scope of entitlement to related research organizations but that has not been done. Therefore, such institutions are probably not "universities" and, unless they employ 50 or fewer

employees, are therefore not "small entities" for the purposes of the Canadian *Patent Rules*.

NOTES

1. SOR/96-423, August 20, 1996, P.C. 1996-1350, August 20, 1996.

2. Section 2.

3. In the Minutes of the Joint Liaison Committee - Patents meeting of February 18, 1997, published at page 204-3 of the Patent and Trademark Institute of Canada Bulletin, the Patent Office stated that it cannot provide guidelines.

4. R.S.C. 1985, c.P-4, as amended.

5. *Merriam Webster's College Dictionary*, 10th Edition, Merriam Webster: Springfield, MA, 1993.

6. *Canadian College Dictionary*, Fitzhenry & Whiteside: Toronto, 1989.

7. *Nouveau Petit-Le Robert* Dicorobert Inc.: Montreal, 1993.

8. *Reading & Bates Construction Co. v. Baker Energy Resources Corporation*, [1986] 8 C.I.P.R. 250 (Federal Court, Trial Division), at page 283.

9. *St. David's College, Lampeter v. Ministry of Education*, (1951) 1 All E.R. 559 (Chancery), per Vaisey, J., at page 560.

10. *State v. Erickson*, 244 P. 287 (S.C. Mont. 1926), *St. David's College, Lampeter v. Ministry of Education*, *supra* at note 9, at page 561.

11. *St. David's College, Lampeter v. Ministry of Education, supra*, at note 9, at page 562.

12. *Roach v. Board of Trustees of St. Louis Public Schools*, 77 Mo. 44.

13. *Commonwealth v. Banks*, 48 A. 277 (S.C. Pa. 1901) at page 278; and *Ingram v. Texas Christian University*, 196 S.W. 608 (C.C.A. Tex 1917).

14. *City of Cincinnati v. Jones*, 16 Ohio Dec. 343.

15. *Re City of London and Ursuline Religious of the Diocese of London*, (1964) 1 O.R. 587 (Court of Appeal); *West v. Board of Trustees of Miami University and Miami School*, 181 NE. 144 (C.A. Oh. 1931); and *Commonwealth v. Banks, supra*, at note 13, at page 278.

16. *Id.*

17. *University of Western Ontario Act*, S.O. 1955, c.118, Subsection 6(2).

18. *University of Western Ontario Act, supra*, at note 17, Paragraph 39 (1) (d).

19. Then R.S.O. 1960, c.23.

20. *Assessment Act, supra*, at note 19, Paragraph 4 (4).

21. *Re City of London and Ursuline Religious of the Diocese of London, supra*, at note 15.

22. *Supra*, at note 9.

23. *St. David's College, Lampeter v. Ministry of Education, supra*, at note 9, at pages 559 to 560.

24. *Id.*, at page 560.

25. See the text at note 9.

26. *St David's College Lampeter v. Ministry of Education*, at note 9, at pages 560 to 562.

27. *Re City of London and Ursuline Religious of Diocese of London, supra*, at note 15.

28. *Id.*, at pages 594 and 595.

29. *St. David's College, Lampeter v. Ministry of Education, supra*, at note 9.

30. *Re City of London and Ursuline Religious of Diocese of London, supra*, at note 15, at page 595.

31. [1975] 5 W.W.R. 429 (Alberta Supreme Court (Appeal Division)).

32. *Id.*, at page 437.

33. "Judicial Control over the University," quoted in *Langlois* v. *Rector and Members of Laval University*, (1974) 47 D.L.R. (3d) 674, at page 681.

34. (1978), 84 D.L.R. (3d) 164 (British Columbia Supreme Court).

35. *Id.*, at page 173.

36. [1996] T.C.J. No. 331.

37. R.S.C. 1985, c. E-15, as amended.

38. *City University* v. *Canada, supra,* at note 36, at paragraph 11.

39. *St. David's College, Lampeter v. Ministry of Education, supra*, at note 9, at page 560.

40. *Id.*, at page 561; *Vanek v. Governors of Alberta, supra*, at note 31; and *Riddle v. University of Victoria, supra*, at note 34. *Quaere* technical institutions such as Ecole Polytechnique in Paris, France.

41. *St. David's College, Lampeter v. Ministry of Education, supra*, at note 9, at page 561.

42. *Id.*, at page 561.

43. *Id.*, at page 561.

44. *Id.*, at page 560.

45. *Id.*, at page 562; and *Re City of London and Ursuline Religious of Diocese of London, supra*, at note 15, at page 596.

46. *St. David's College, Lampeter v. Ministry of Education, id.*, at page 562; *Re City of London and Ursuline Religious of Diocese of London, id.*, at page 595; *West v. Board of Trustees of Miami University and Miami School, supra*, at note 15, and *Commonwealth v. Banks, supra*, at note 15.

47. SO 1983, c. 36.

48. *Id.*, Paragraph 2 (a).

49. *Id.*, Section 3.

50. For example, British Columbia's *University Act*, R.S.B.C. 1979, c. 419; and Alberta's *The University Act*, R.S.A. 1970, c.378.

51. For example, *The University of Toronto Act*, 1947, S.O. 1947, c. 112; *The University of Saskatchewan Act*, R.S.S. 1978, c. U-6; *An Act Regulating Dalhousie University*, S.N.S. 1970, c. 147; *University of Manitoba Act*, C.C.S.M., c. U-60; and *University of Regina Act*, R.S.S. 1978, c. U-5.

52. Lewis, Clive B., *The Legal Nature of a University and the Student-University Relationship*, (1983), 15 Ott. L.R. 249, at page 250, note 6.

53. Issued by King George IV at Westminster in 1821 and confirmed and amended by a Charter of Queen Victoria issued at Westminster in 1852 (the author's *alma mater*).

54. Issued by Queen Victoria at Westminster in 1841.

55. *An Act respecting Queen's College at Kingston*, S.C. 1882, c. 123, as amended by S.C. 1912, c. 138.

56. *City University v. Canada, supra*, at note 36.

57. *Re City of London and Ursuline Religious of Diocese of London, supra*, at note 15.

Biotechnology Research & Patent Infringement: Should Research Be Exempt from Charges of Patent Infringement?[1]

David L. Parker*
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I. INTRODUCTION

The last twenty years have seen startling developments in life science technologies that will have far reaching effects on all aspects of our lives. These biotechnologies are emanating from innate drives to understand how diverse, yet interrelated, natural biological systems function, and to detect, characterize, and control these biological systems for beneficial application.[2]

The development of recombinant DNA illustrates a successful attempt to mimic biological processes while combining distinct technologies. Stanley Cohen and others demonstrated in 1973 that diverse genetic elements could be recombined in a test tube and replicated in a host cell, relying on the earlier discovery of restriction enzymes.[3] The ability to replicate recombined DNA segments, in turn, served as a foundation for many later discoveries, such as the efficient characterization and sequencing of large DNA segments[4] and the expression of

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genetic elements in recombinant host cells.[5] Recombinant DNA technology also led to innumerable direct applications, including the development and production of a host of pharmaceutical, diagnostic, agricultural, and industrial products and procedures.[6] The historical development of other life science technologies is not unlike that of recombinant DNA, each built upon a latticework of earlier discoveries and providing support for future innovations.

However, biotechnological inventions must be substantially tested, refined, scaled up, and otherwise adapted before they can be made available to the public. These activities are associated with substantial costs, often well beyond those of the basic research, particularly for biotechnological inventions that have some direct use other than as research tools, such as biological pharmaceuticals. Moreover, the basic laboratory discovery often serves only as a model or starting point for the development of a commercial product or process.

The development of purified, concentrated human clotting factor VIII:C by Drs. Zimmermann and Fulcher at Scripps Clinic and Research Foundation illustrates the difficulty of transforming a biotechnological discovery into a commercial success.[7] Although there is a significant market for purified human Factor VIII:C, the Scripps' process is not commercially desirable. Human plasma must be employed as a starting material, requiring large donor pools.[8] Nevertheless, the Scripps' process served as a starting point for Genentech scientists in their development of recombinant human Factor VIII:C that can be readily commercialized.[9] After the issuance of the Scripps patent, Genentech enlisted the assistance of a laboratory in England to produce human Factor VIII:C using the patented process.[10] This purified Factor VIII:C was then imported into the United States. Genentech scientists were able to isolate the Factor VIII:C gene, characterize its structure and sequence, and use it for recombinant production of the protein.

The dual role of biotechnological discoveries as research tools and as commercial products and processes raises the significant issue of whether early stage or laboratory scale developments should receive broad patent protection or be made freely available for others to use. The right to use a patented invention for research and development is a concern in both commercial and university settings.[11] Due to the vagaries of the common law research exemption, research having some attenuated commercial purpose may be subject to charges of patent infringement, even where the research is in the early stages far removed from the final product or where the research is being conducted by a university or other noncommercial entity.[12]

Aside from the possible applicability of the limited FDA exemption of the patent statutes,[13] case law currently affords only a narrow exemption for research that is generally unavailable where the research use is any way commercial or within the legitimate business of the alleged infringer.[14] The line between commercial and noncommercial biotechnological research is increasingly blurred: virtually all research could be interpreted as within the legitimate business of the user or as having some commercial purpose.[15] Furthermore, the importance of biotechnological advances as building blocks for further advancement, coupled with the limited availability of federal research funds for basic research and the expense of basic and developmental research, have contributed to the increasing interdependence of basic researchers and commercial entities.

Also blurring the distinction between commercial and noncommercial research is the federal government's commitment to promote the development and utilization of patent rights in inventions developed using federal funds—what typically might be referred to as noncommercial research—and to encourage stronger ties between organizations conducting federally funded research and commercial organizations. For example, Congress passed the 1980 Patent and Trademark Act

to promote the development of inventions arising from federally supported research and development.[16] This Act allows small business entities and nonprofit organizations, such as universities and research institutions, to retain title to inventions developed in whole or part with federal funds. This law, along with the Technology Innovation Act of 1980,[17] positively affirms the right, if not the obligation, of publicly funded research entities to retain title to their inventions and provide for their development.

Many countervailing considerations influence how much and what kinds of research using another's patented invention should be "free." Which research is best encouraged by protecting it from a charge of infringement, and which is not? Commentators generally espouse one of three possible views: (1) no exemption is ever justified; (2) an exemption is justified for purely philosophical, noncommercial research; or (3) an exemption is justified for research efforts that result in significant technological advances or innovations. However, most commentators agree that research on a patented invention to produce an improvement in the technology or to design around the invention should be encouraged by ensuring that this type of activity is not considered infringement.[18]

Those favoring a narrow exemption or no exemption at all (categories 1 & 2) generally rely on the underlying premise of patent systems—the availability of protection for inventions stimulates innovation.[19] Allowing commercial endeavors the free use of early-stage inventions to improve upon and design around basic patents in the development of commercial products evades the protection afforded by the original patent and denies the incentives of the patent system to a class of inventions that play an important role in innovation.[20] All innovations, whether research or end-product oriented, advance important societal goals, and the value of these innovations is purportedly best left to the marketplace where subsequent innovators may or may not choose to take advantage of the discoveries.[21]

Those in the third category feel strongly that the advancement of basic research and technological innovation would be better served by allowing the free use of patented inventions in research and experimentation.[22] Most would permit an experimental exemption for use that results in further innovation, such as in the development of a product outside the scope of the patent.[23] Some commentators in favor of an exemption, however, fail to distinguish between uses of research tools to prepare distinct innovations outside of the scope of the patent in question (e.g., the use of a patented screening assay to identify cancer drugs), and uses that result in improvements to the patented technology (e.g., the use of Scripps' human Factor VIII:C in the preparation of recombinant Factor VIII:C).[24] The distinction between research *using* a patented invention and research *on* a patented invention is difficult, yet vital. If some commercial research should be freely allowed, some provision must be made for inventions having significant research applications.[25]

By their nature, patent systems attempt to stimulate innovation through the use of a reward system that gives the right to exclude others from making, using, selling, or offering to sell the patented invention for a defined period of time.[26] Our own Constitution grants Congress the power "to promote the progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[27] We want to encourage inventors to improve upon what those before have achieved, yet at the same time we want to promote innovation by conferring on inventors the full right of exclusion to which they are entitled. While both policies are concerned with achieving the same end—innovation—at times they are seemingly in direct and irreconcilable conflict. Nowhere are they more in conflict than in the case of patented inventions having a significant, if not sole, usefulness in conducting research.

Who would deny the inventor of the microscope—an invention suited particularly for research—the right to a patent on that

microscope that grants the full right to exclude others from using it? If achieving the ultimate goal of research —innovation—is important, then enhancing the ability to achieve that goal more efficiently has a comparable intrinsic value. Thus, the ability to enhance the progress of research should be just as important to our society as the ultimate goal of that research. If the microscope promotes invention, then its use to achieve invention merits recognition and compensation, if only through the sale of that microscope over some other inferior research tool. Similarly, if a transgenic mouse can be used to identify a cancer cure or bring it to the market even one year earlier, then its use to achieve invention should be similarly recognized and compensated.

In the following sections, this paper will review briefly the genesis of the common law research exemption doctrine in the United States and discuss the research exemption of 35 U.S.C. § 271(e)(1) and its judicial interpretation. The article concludes with a consideration of various proposals from the commentators, along with the authors' recommendations.

The analyses below will be undertaken with reference to two hypothetical scenarios that have been chosen to highlight the difficulty of distinguishing between different types of research uses of biotechnological inventions. In one scenario, a hypothetical patent covers the use of a genetically engineered recombinant host cell in a screening assay for identifying new therapeutic agents.[28] For the purposes of this scenario, the assay is the only utility associated with these recombinant host cells. This scenario is not unlike that of the transgenic mouse whose only utility is as a model system for studying cancer or screening for novel pharmaceuticals.

In the second scenario, the patent in question covers a recombinant gene useful in the production of a pharmaceutical product. Here a competing pharmaceutical company produces the gene to study its structure. After its structure is characterized, the company prepares a mutant gene and must

use the patented gene in the one-time isolation procedure of the mutant gene. This scenario is not unlike that presented by the Scripps Clinic case, where Genentech scientists used the patented Scripps' isolation procedure. However, whereas the Genentech scientists merely studied the Factor VIII:C to determine its structure, here the patented gene is actually employed to isolate the improved mutant product.

II. THE RESEARCH EXEMPTION IN THE UNITED STATES

A. Development of the Judicially-Created Experimental Use Exemption[29]

The United States research or experimental use exception to patent infringement finds its roots in two early opinions authored by Supreme Court Justice Story while acting in his circuit appellate capacity in *Whittemore v. Cutter*[30] and *Sawin v. Guild*.[31] In *Whittemore*, Justice Story focused on an intent to use for profit:

> [T]he making of a machine fit for use, and with a design to use it for profit, was an infringement of the patent right. . . . [I]t could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.[32]

Sawin, which involved a charge of infringement against a deputy sheriff who had seized certain patented machines to satisfy a judgment debt, contains similar language directly referring to an intent to use for profit as a requisite for infringement:

> [The infringement] . . . must be the making with an intent to use for profit and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification . . . . In other words, the

> making must be with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery.[33]

Sawin has often been cited for establishing a two-part test for the experimental use exemption: (1) the activity must be for philosophical experiment or for ascertaining the adequacy of the disclosed invention; and (2) the activity must not be carried out with an intent to use for profit.[34] This is a broad reading of *Sawin* on its facts. Another justifiable interpretation is that any use that is not *itself* a use for profit is not an infringement, with "philosophical experiment" and "determining the adequacy of the disclosure" being merely two examples of uses that are not considered "for profit." After all, the sale by the deputy sheriff was neither philosophical nor an investigation into the patent disclosure. While the principle forwarded by *Sawin* and *Whittemore* is that infringement requires a "profit intent" in a use of the invention, these cases do not address the question of how closely connected the intent must be to the profit.

Professor Robinson in his 1890 treatise, which is referred to or relied upon in virtually every subsequent case to consider this exemption, provides further guidance on an intent to use for profit:

> [t]he interest to be promoted by the wrongful employment of the invention must be hostile to the interest of the patentee. The interest of the patentee is represented by the emoluments which he does or might receive from the practice of the invention by himself or others. ... Hence acts of infringement must attack the right of the patentee to these emoluments, and either turn them aside into other channels or prevent them from accruing in favor of anyone. An unauthorized sale of the invention is always such an act. But the manufacture or the use of the invention may be intended only for other purposes, and produce no pecuniary result. Thus, where it is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee

> are not antagonized, the sole effect being of an intellectual character in the promotion of the employer's knowledge or the relaxation affected to his mind. *But if the products of the experiment are sold, or used for the convenience of the experimenter, or if the experiments are conducted with a view of the adaptation of the invention to the experimenter's business*, the acts of making or of use are violations of the rights of the inventors and infringement of his patent.[35]

Robinson takes a restrictive view of the exception by proposing that experiments "conducted with a view to the adaptation of the invention to the experimenter's business" are not covered by the exemption. However, Robinson does refer to an "employer," recognizing that some types of research activities may properly be undertaken as experiments by commercial firms.[36] Professor Cooper in his treatise suggests that Robinson is recognizing the existence and protectability of inventions whose use is intended for *conducting* research.[37] Nevertheless, while *Sawin* could be interpreted to focus upon an intent to profit *directly* from the particular complained-of use of the patented invention, Robinson narrows the exemption by excluding acts that have a business purpose but not an immediate profit intent.

Much of the twentieth-century case law dealing with the experimental use exception emanates from the Court of Claims and involves infringement actions against the United States government.[38] The issue often arises in actions against the U.S. because the profit intent element is typically absent. The earlier Court of Claims cases strained to find that the exception applied,[39] whereas in more recent cases the defense has been disallowed with the exception defined quite narrowly.[40]

In these recent cases, such as *Pitcairn v. United States*, the court has consistently applied Professor Robinson's inquiries, refusing to find that the government's use of

the accused devices was "for amusement, to satisfy idle curiosity, or for philosophical inquiry" if the use was for the "legitimate interests" of the government.[41] This represents a significant narrowing of the experimental use exception, suggesting that even if no profit motive is attached to the experimental activity, the activity will nevertheless be infringing if within the legitimate business of the organization. Unfortunately, while this implies that some business uses are permissible, there is no discussion of what types of research would not be within an organization's legitimate business. Returning to the scenario involving the mutation of a patented gene, studying the structure of the patented gene to ascertain how to prepare useful mutations appears to be within the legitimate business of the company. However, under the Story analysis, ascertaining the function of the invention would be a permissible use. Presumably a court would find that infringement exists where the activity is for the convenience of the experimenter or if the experiments are conducted with a view to the adaptation of the invention to the experimenter's business.

This narrow interpretation of the experimental use exception even applies to a nonprofit organization. In *Ruth v. Stems-Roger Manufacturing Co.*,[42] the defendant sold two milling machines and replacement parts to the Colorado School of Mines.[43] The court held that, while the original sale of equipment was infringing, the sale of replacement parts was not contributory infringement because the laboratory use of the machines by the School of Mines was for experimental purposes.[44] The decision noted that certain sales of parts to the School of Mines were for nonexperimental purposes and therefore infringing.[45] Thus, the court did not consider a blanket exemption for schools or nonprofit organizations, instead looking to the machines' actual use. Parts sold to the school while the machines were being used for

laboratory teaching were found to be noninfringing sales.[46] Carrying *Pitcairn* to its logical conclusion, is it not the case that this type of experimentation is within the legitimate business of the school? What if the school had received grant support from the defendant manufacturing company, or the educators at the school routinely provided feedback to the company regarding the operation of the defendant's machines?

The Federal Circuit's only detailed pronouncement on the experimental use exception is *Roche Products, Inc. v. Bolar Pharmaceutical Co.*[47] The court found infringement in the use of a patented drug in FDA-required studies, holding the experimental use exception "to be truly narrow" and endorsing the "legitimate business" language of the Court of Claims.[48] *Roche Products*' vitality is questionable in light of the subsequent enactment of the Drug Price and Patent Term Restoration Act of 1984.

Turning to the first hypothetical of the patented drug screening assay, resolution of the infringement issue is fairly straightforward. The assay is being used with a profit intent—the intent to identify a commercial product. Under *Pitcairn,* use of the assay would appear to be within the legitimate business of the company, so the exemption is unavailable. Difficulty arises where the assay is employed by a university researcher to identify novel pharmaceuticals. *Ruth* supports a conclusion that such an act is not protected by the experimental use exemption unless the use is carried out in conjunction with educational activities. Thus, a court would be expected to look to the circumstances of the particular use: for example, whether it was being performed for a commercial entity. However, the issue is complicated where there are dual purposes, such as where the researcher is conducting the infringing screening activities in support of his NIH grant as well as to

commercially license the results for additional research support.

A further complication arises where the development and infringing use of the patented assay were funded with federal monies, such as NIH grants.[49] This hypothetical raises two distinct questions. First, 35 U.S.C. §202(c)(5) provides that, with respect to inventions funded by federal monies of which the nonprofit organization elects to retain title, "the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid up license to practice or have practiced for or on behalf of the United States [the] subject invention." Does the awarding of a federal research grant carry with it an implied license of these retained rights that the governmental agency has in other grant-funded inventions? Alternatively, can the federal agency explicitly license these retained rights in conjunction with the awarding of a research grant by executing a written statement authorizing the potential infringer to practice any inventions in which the government has such rights on the behalf of the United States? The answer to the question of the implied license is probably no.[50] However, the answer to the latter question is more uncertain. A second related, yet distinct, issue is whether the infringing acts of the researcher, conducted with either an express or implied license, can be attributed to the U.S. such that the patentee must sue the U.S. in the court of claims pursuant to 28 U.S.C. §1498.[51] This could arise, for example, were the federal agency to authorize the researcher to pursue the research plan detailed in the grant on behalf of the federal government, and this research plan required the infringement of a patent in which the federal government did not have retained rights.[52]

While the first hypothetical of the screening assay involves an invention whose primary use is for research,

the second hypothetical involves an invention having a direct commercial application, being used for its research applications. The latter activity could arguably fall within Story's exception for ascertaining the verity and exactness of the specification. However, the patented gene is also being used for the convenience of the experimenter and has been adapted to the experimenter's business. The outcome of this conflict is difficult to predict under the current case law.

Where the patented gene is actually used in the isolation of the gene encoding the improved pharmaceutical, this removes the possibility that the activity was to ascertain the verity and exactness of the specification and reinforces a conclusion that the use was "for profit" and therefore infringing. Proponents of a broader exemption point to this result to illustrate the need for a stronger exemption—one that would clearly allow research resulting in design-arounds or improved products.[53] In contrast, the novel pharmaceutical identified in the first scenario through the use of the patented screening assay would not have been a design-around or improvement of the technology in question—the assay. Moreover, there is no apparent reason to distinguish between the two scenarios in terms of which activity merits encouragement because each results in the identification and selection of a novel pharmaceutical. The fact that one is a design-around made by research *on* a patented invention, and the other developed by research *using* a patented invention, is of no import.

B. Section 271(e)(1) Statutory Exemptions

Congress passed the Drug Price and Patent Term Restoration Act of 1984[54] to balance the interests of the pharmaceutical companies involved in the development of new pharmaceuticals with those of the generic manufacturers.[55] The Act intends to provide drug

companies with the ability to recapture a portion of the "front end" of the commercial life of their patent protection, which is lost during the FDA approval process, while allowing generic manufacturers the right to proceed with premarket approval testing during the life of the relevant patent(s) so that they may commercialize their products on the patent's expiration.

Unfortunately the wording of the enacted provisions is unclear, leading to an abundance of confusion and speculation by courts attempting to define its boundaries. Section 271(e)(1) states:

> It shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs or veterinary biological products.

The Federal Circuit in *Eli Lilly & Co. v. Medtronic, Inc.*, considering the scope of "patented inventions" exempted under § 271(e)(1), held that it "allows a party to make, use, or sell *any type* of 'patented invention' if 'solely' for the restricted uses stated therein."[56] The Supreme Court affirmed, focusing on the complementary nature of the Drug Price Act, which "sought to eliminate th[e] distortion[s that occur at] both ends of the patent period" where government regulatory approval is required to market the "patented invention."[57] The Court concluded that the "patented inventions" that are subject to exemption under § 271(e) are those same inventions that are subject to regulatory approval and hence patent term extension.[58]

In a series of recent opinions, the Federal Circuit has signaled an expansion of the § 271(e)(1) exemption by looking objectively to the "uses" of the patented invention.[59] First, it must be determined whether these uses are infringing uses under § 271(a).[60] Only if the

alleged acts are otherwise infringing is it necessary to assess whether any such act is reasonably related to the development of information for submission to federal agencies.[61]

The first court to interpret the statute held that the exemption was narrow, only applying where the defendant had no purpose in its use of the patented invention except FDA testing and submissions.[62] The vitality of this holding is questionable. In a well-reasoned opinion implicitly adopted by the Federal Circuit,[63] the Northern District of California interpreted the statute broadly, without mentioning this earlier, contrary holding.[64] In *Intermedics*, the defendant, Ventritex, was accused of infringement by carrying out various activities with its implantable defibrillator, including using test data to support import licenses in foreign countries; authorizing the publication of articles; using the data to raise capital; demonstrating the device at scientific meetings and trade shows; and filing foreign patent applications.[65] In its two-step analysis, the court first found that most of these acts—uses of test data in submissions to foreign governments, in preparing a prospectus for investors, and in publications and patent applications—were "collateral" uses of data, not infringements under section 271(a), and thus irrelevant.[66] The court then considered those specific acts that could, but for the exemption, be infringing under § 271(a), such as sales to hospitals in the United States, sales to international distributors, tests of the device in the U.S. and abroad, and demonstrations of the device at trade shows. Each of these uses was found to be "reasonably related" to the submission of information to the FDA, protected under § 271(e)(1).[67] The remaining § 271(e)(1) cases are consistent with the *Intermedics* case, further expanding the list of permissible "uses."[68]

There are still disturbing aspects of the § 271(e)(1) language that could have a significant impact upon basic patents of the biotechnology industry, as illustrated by the two hypotheticals. Under the first scenario of the assay, the plain wording of § 271(e)(1) would appear to provide a reasonable basis for arguing that using the assay to screen for a drug is a protected activity. If the use of an otherwise infringing screening process is reasonably related to the gathering of information for FDA submission, the screening activity would appear to fall within the literal scope of § 271(e)(1). However, the "patented invention" being used is not the drug itself, but the patented screening assay. The investigator is not "testing" the *assay* for FDA approval purposes, he is testing the *drug using the patented assay*. While it is unlikely Congress intended to provide an exemption for inventions other than the one for which government approval is being sought, a plain reading of the statute does not require this.

The case law also does not adequately answer this question. In *Eli Lilly*, the Supreme Court initially observed that the scope of the phrase "patented invention" is commensurate with "all inventions," stating that "[t]he phrase patented invention in section 271(e)(1) is defined to include all inventions, not drug-related inventions alone."[69] This interpretation would include the use of a patented drug screening assay even though no FDA approval is being sought for the "patented invention" (the assay) itself. However, *Eli Lilly* also suggests that "patented invention" under § 271(e)(1) is at least limited to those same inventions for which patent term extension is being sought.[70] In fact, it is reasonable to conclude that the court limited the coverage of §271(e)(1) to those inventions for which government reporting requirements exist and for which patent term extension is available. This implies that there is a

limitation on the scope of "patented inventions" covered under § 271(e)(1).

The second research scenario of the patented gene presents a somewhat different set of problems. Focusing only on whether one or both of the hypothetical uses of the patented gene are covered by the § 271(e)(1) exemption, the first consideration is whether these activities are "uses" under § 271(a). Assuming that at least one of these uses would fall within the scope of §271(a), it is again unclear whether either or both uses would be exempt from infringement under § 271(e)(1). Although the use of the gene is farther removed from the information that is ultimately submitted to the FDA than were those uses that have been addressed by the courts, it nevertheless appears to be reasonably related to that end. There is some question regarding the applicability of § 271(e)(1) where the "patented" product that is used is distinct from the product for which FDA approval is being sought, and the patent does not cover the product subject to FDA approval.

If a § 271(e)(1) exemption is found to apply to any of the foregoing scenarios, it could have significant consequences for biotechnological patents, particularly those intended principally for research applications. If these acts of infringement are exempted, these patents are virtually incapable of being infringed. It is, for example, unlikely that the cancer drug itself would be found to infringe the assay patent. This contrasts the usual § 271(e)(1) situation where an existing patent tempers the infringer's ability to commercialize after the patent term has expired.

III. PROPOSALS

Numerous approaches to the creation of a research exemption have been proposed and adopted throughout the world. All of

these approaches have a significant number of potential drawbacks associated with them in light of the biotechnology hypotheticals. For example, the common law approach in the United States suffers from substantial uncertainty as to its scope and applicability, as evidenced by the prevailing Court of Claims case law that would appear to foreclose its applicability in most, if not all, situations.[71] The approach represented by §271(e)(1) is now being interpreted broadly, and could have significant consequences if extended to apply to the use of research inventions in the development of drug and medical products. Such inventions may achieve their benefits after only limited use that could go entirely without recompense. Furthermore, the approach codified in many foreign jurisdictions, which allow experimentation *on* a patented invention as long as the research relates to the subject matter of the invention but do not allow research *using* the same patented invention, fails to adequately account for inventions that may have both research and direct applications.[72] If an exemption for commercial or university research and development is needed to promote continued innovation—an opinion not necessarily held by the authors—then any such exemption must take into account the fact that inventions, particularly life science inventions, typically have dual roles as stepping stones and as commercial products and processes.

Additionally, the need for some sort of an exemption for commercial research and development is unclear. One of the driving forces behind a statutory research exemption is the desire by university and research institutions to be free from risk of infringement exposure. However, there are significant practical, legal, and economic reasons why it is unlikely that universities and research entities, even those actively involved in obtaining and licensing patents, will ever be subject to more than incidental risk.[73] Practically speaking, it would be poor policy for a patentee corporation to bring an infringement suit against a research institute, and such a suit would likely be difficult to win in a jury trial. Economically the expense of patent litigation, coupled with the limited nature of damages

arising out of research activities, would limit patent infringement actions against research institutions to only the most significant matters. Moreover, from a legal standpoint, a court would be much more likely to find that the case law exemption applies. This is true even where the research institute has an active patenting and licensing program.

Ironically, a statutory research exemption could have a negative effect on research institutions that have active patent and licensing programs or receive research funds from commercial entities that want to protect their investments. A significant number of patents that arise out of basic research institutes cover subject matter that is only a starting point for further development of commercial products or involve techniques or compositions whose principal value to commercial licensees is the ability to improve research capability. A statutory research exemption could thus undermine the value of these basic patents by rendering them essentially incapable of being infringed.

If an exception for "commercial" research and development is warranted, an alternative that provides an exception for new product development while maintaining the basic innovative stimulus provided by a strong patent system is as follows:

Research or Experimentation Using a Patented Invention

(a) No action for patent infringement shall lie under section 281 of this title, and no injunction under section 283 of this title shall be entered, with respect to the making or using of a patented invention in research or experimentation, or in the development of an invention or discovery.

(b) The sale or offering for sale of any product or process developed under the provision of section (a) hereof shall constitute an act of infringement of any patent covering a patented invention used in the development of such a product or process.

(c) In any action for infringement to which this section is applicable:

(1) the time limitation provisions of section 286 shall be tolled until a sale or offer for sale of any such product or process.

(2) no injunction under section 283 of this title shall be entered against the sale or offer for sale of any product or process developed under the provisions of subsection (a) hereof.

(d) This section does not apply to a patented invention to which section 271(e)(1) or this title applies.

This allows the commercial use of a patented invention in research and development and only makes this commercial research subject to infringement charges if the outcome of that research is ultimately commercialized through sale or offer for sale. In short, only the research activities would receive the "limited-time" protection, not the end result of that research. If the research is truly philosophical in nature and hence never commercialized, it will never be subject to a charge of infringement under the proposed statute.

However, upon commercialization, the sale or offer for sale of any product or process developed through the use of a patented invention would be actionable, whereas the underlying research acts giving rise to the commercialized product or process would not. Presumably the contribution of the original invention to the development of the product or process would be reflected in the damages assessed. Significant research contributions to the commercialized product or process would reap significant damages, while limited or incidental contributions would realize limited, if any, damages. Of course, if the activity results in a product or process within the scope of the patented technology, the end product or process itself would be actionable without regard to the underlying technology used in its development.

The concerns of research institutions are remedied in that their research, *per se*, would never be subject to a charge of infringement, although the resulting commercial product or process would be subject to a charge of infringement. Research-

based patented technologies would also have a statutorily recognized position within the patent system. Thus, use of the patented drug screening process set forth at the beginning of this article in the commercial identification of pharmaceuticals would not be actionable, but sale of the resulting identified drug would be actionable. Similarly, the use of the patented gene to isolate the improved mutant gene would not be actionable, but commercialization of the improved gene might well be an infringement.

A potential trouble area would be those uses where the patented technology was merely "studied," but not actually "used." It is presumed, however, that this would be dealt with in one of two ways: either the use would be viewed as minimal, resulting in minimal damages, or the use would not in fact be a "use" for the purposes of § 271(a).[74] A similar problem arises where the researcher merely reverse engineers or studies the original patented invention, finds it unsuitable for his purposes, and proceeds to develop an improved invention outside the scope of the original patent without the use of the original invention. While an issue might be raised that the original reverse engineering was somehow *using* the invention, this would not be *using* the invention "in the development" of the product or process.

What about the effects of such a statute on patented research products?[75] Would the proposed statute adequately protect the interests of biotechnology companies whose patented technologies must be deposited with a culture depository and as such are accessible to research interests without direct compensation? While this is a potential problem area, a truly "philosophical" and "academic" use would not be infringing while any commercial use of the deposit could be tainted. If there is any ultimate commercial application, then the "fruit of the poisoned tree" doctrine, whereby any product or process developed using the deposited material would be subject to infringement, could dictate that the material be accessed properly through available commercial channels. In this manner

the "first sale" doctrine would remove any taint from the resulting product or process.[76]

A provision is also included to toll the six-year limitation provisions of 35 U.S.C. § 286 to reinforce the concept that a product developed through the unlicensed use of a patented invention would not escape liability merely because it is commercialized many years after the original use of the infringing technology. To ensure that the products of such research remain available to the public, a provision is included to prevent the issuance of an injunction. Of course, such a prohibition against an injunction would not be available where the product or process so developed actually infringes the basic patent.

By avoiding quantitative or qualitative terms such as "reasonably related," the proposed statute avoids the most common problems associated with statutory drafting where the intent of the drafter must be interpreted. The only relevant issues here are whether the patented invention was used in the development of the product or process and whether the product or process was sold or offered for sale.

IV. CONCLUSION

There can be no doubt that innovation is promoted through the granting of valid patents. However, basic inventions that serve as valid starting points for further development, as well as those directed to improving our ability to innovate, such as those directed to the microscope, new drug screening assays, or patented genes, are equally important to our technological advancement. Thus, any exemption for research should provide for inventions with a primary utility as a research tool and should carefully balance the need to promote incentives to seek patent protection for basic technologies with the need to decrease the costs associated with research on, and for purposes of, assessing that basic technology. While some provision for research and development free from a charge of infringement

would be conducive to unfettered innovation, providing free reins to the commercial exploitation of such inventions could ultimately serve to frustrate the very aims intended to be achieved.

NOTES

1. This article is related to David L. Parker, *Patent Infringement Exemptions for Life Science Research*, 16 HOUS. J. INT'L L. 615 (1994).

2. For an excellent historical account of the major discoveries in molecular biology and their interrelations, see HORACE F. JUDSON, THE EIGHTH DAY OF CREATION: THE MAKERS OF THE REVOLUTION IN BIOLOGY 239-40 (1979) (profiling the leading scientists responsible for the revolution in molecular biology and describing their approach as scientific method combined with personal ambition).

3. Stanley N. Cohen et al., *Construction of Biologically Functional Plasmids In Vitro*, 70 PROC. NAT'L ACAD. SCI. USA, 3240 (1973). *See also* Hamilton O. Smith, *Nucleotide Sequence Specificity of Restriction Endonucleases*, 205 SCI. 455 (1979); Daniel Nathans and Hamilton O. Smith, *Restriction Endonucleases in the Analysis and Restructuring of DNA Molecules*, 44 ANN. REV. BIOCHEMISTRY 273 (1975).

4. *See, e.g.*, Allen M. Maxam and Walter Gilbert, *A New Method for Sequencing DNA*, 74 PROC. NAT'L ACAD. SCI. USA 560 (1977).

5. *See, e.g.*, Keith Bachman and Mark Ptashne, *Maximizing Gene Expression on a Plasmid Using Recombinant DNA* In Vitro, 13 CELL 65 (1978).

6. *See, e.g.*, VANDER S. LUCIANO, HUMAN PHYSIOLOGY 73 (5th ed. 1990); Michael S. Greenfield, Note, *Recombinant DNA Technology: A Science Struggling with the Patent Law*, 44 STAN. L. REV. 1051, 1052 (1992).

7. *See Scripps Clinic & Research Found. v. Genentech, Inc.*, 666 F. Supp. 1379 (N.D. Cal. 1987), *aff'd*, 927 F.2d 1565 (Fed. Cir. 1991).

8. *Id.* at 1383-84.

9. *Id.* at 1384.

10. *Id.*

11. *See* HAROLD C. WEGNER, PATENT LAW IN BIOTECHNOLOGY, CHEMICALS & PHARMACEUTICALS § 355, at 256-68 (1992).

12. *See infra* notes 29 to 53 and accompanying text.

13. The limited exemption available under 35 U.S.C. § 271(e)(1) provides that it "shall not be an act of infringement to make, use, or sell a patented invention... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs." *See infra* notes 55 to 70 and accompanying text.

14. Jordan P. Karp, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169, 2171-74 (1991).

15. Suzanne T. Michel, Comment, *The Experimental Use Exception to Infringement Applied to Federally Funded Inventions*, 7 HIGH TECH. L.J. 369, 383-86 (1993).

16. *See* Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified at 35 U.S.C. §§ 200-212 (1988 & Supp IV 1992)).

17. Pub. L. 96-480, 94 Stat. 2312 (1980) (codified at 15 U.S.C. §§3701-14 (1988 & Supp IV 1992)). The Technology Innovation Act is intended to promote technological innovation for commercial and public purposes, particularly discoveries and advances funded by the federal government. To achieve this end, the Act established the National Institute of Standards, the National Technical Information Service, Cooperative Research Centers, laws facilitating the transfer of federally owned technology, and cooperative research agreements and grants.

18. *See* Ronald D. Hantman, *Experimental Use as an Exception to Patent Infringement*, 67 J. PAT. OFF. SOC'Y 617, 644 (1985), or by providing that such research or its products are subject only to a reasonable royalty payment to the patentee, *see* Irving N. Feit, *Biotechnology Research and the Experimental Use Exception to Patent Infringement*, 71 J. PAT. OFF. SOC'Y 819, 840 (1989); Karp, *supra* note 14, at 2169; Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1074-1078 (1989).

19. *See* Richard E. Bee, *Experimental Use as an Act of Patent Infringement*, 39 J. PAT. OFF. SOC'Y 357 (1957) (arguing that the

experimental use exception should be strictly construed and held inapplicable where a business purpose or profit motive exists); *Transgenic Animal Patent Reform Act: Hearings before the Subcomm. on Courts, Intellectual Property, and the Admin. of Justice of the House Comm. on the Judiciary*, 101st Cong., 2d Sess. (1989) 189-90, *microformed on* 90-H521-57 (Congressional Info. Serv.) [hereinafter Transgenic Act Hearings] (discussing a letter from Donald J. Quigg, Assistant Secretary and Commissioner of Patents and Trademarks, to Representative Robert W. Kastenmeyer that stated the exemption could diminish the strong incentive of the patent system).

20. *See* Michel, *supra* note 15, at 394-397 (noting that a broad exception harms incentives to invent due to "free riding" which reduces incentives; unjustly deprives the patentee of royalties; and reduces the free exchange of ideas by causing a reluctance to seek patent protection); Eisenberg, *supra* note 18 (arguing that policy reasons for an exemption are weakest for using inventions with a primary utility for research and strongest for using the invention to assess its function and sufficiency with a gray area where the invention is used as a starting point for the development of innovations outside the scope of the original patent).

21. *See* Bee, *supra* note 19, at 366 (arguing that research injures the patentee in that he has failed to acquire at least a "just and deserved royalty from the experimental user").

22. In its report on Title IV of the proposed Patent Competitiveness and Technological Innovation Act of 1990 (H.R. 5598), the House Committee on the Judiciary recommended a broad research exemption on the basis that the use of patented inventions to produce improvements as well as to develop innovations outside the scope of the patent encourages innovation, avoids unnecessary litigation, eliminates confusion regarding the law, and promotes closer ties between public research and private industry. H.R. REP. No. 960, 101st Cong., 2d Sess. 41-45 (1990), *microformed on* CIS No. 90-H523-40 (Congressional Info. Serv.) [hereinafter Patent House Report].

In its 1988 American Bar Association committee report, the Section of Patent, Trademark & Copyright Law, at 25-28, pointing to Genentech's development of recombinant Factor VIII:C using the underlying Scripps technology, passed a resolution favoring "an exemption from infringement for experimental or research use, not limited to pharmaceutical products, whether or not such use is conducted by a commercial organization."

See also Ned A. Israelsen, *Making, Using, and Selling Without Infringing: An Examination of 35 U.S.C. Section 271(e) and the Experimental Use Exception to Patent Infringement*, 16 AM. INT. PROP. L. ASS'N Q.J. 457 (1989) (suggesting that scientific progress requires access to the improvements of others for peer review and data building functions and the denial of access to freely use earlier technologies is wasteful by requiring the second comer to design around the technology).

23. Hantman, *supra* note 18, at 644, believes that the existing experimental use exception ought to be available for commercial research activities "while developing new uses and improvements" as long as there is no attempt to make a profit "during" the infringement. Hantman *does* make the distinction between experimental use *on* a patented invention and use of a patented invention *for* experimental purposes, using the following analogy:

> For example, research on a patented computer may result in improvements to the computer. But research with a patented computer in, say, biology, will not result in improvements to the computer . . . [and] it ought not be excused even if the biology research is done for philosophical experiment by a university.

Id. at 639.

24. For example, in its recent consideration of a research exemption bill, Congress recognized Hantman's distinction between research *on* a patented invention and research *using* a patented invention, yet proposed a statute that would appear to allow research *using* a patented invention so long as the end result was outside the scope of the patented invention, *i.e.*, so long as it was a successful design-around. Patent House Report, *supra* note 22, at 41, 65-66.

25. Feit, *supra* note 18, at 821, illustrates this point by reference to an article by Jeffrey L. Fox (*Patents Encroaching on Research Freedom*, 224 SCIENCE 1080, 1080 (1984)), in which Fox describes infringement warning letters sent by Johnson & Johnson patent counsel to individuals, including several universities and the National Institutes of Health (NIH). These parties had obtained samples of patented hybridomas deposited with the American Type Culture Collection (ATCC). The NIH reportedly responded that its use of the patented hybridomas was "experimental" and thus not infringing. Feit correctly observes that Johnson & Johnson's interests are harmed when anyone obtains such a sample from the ATCC instead of purchasing it.

26. *See* 35 U.S.C. § 271(a).

27. U.S. CONST. art. I, § 8, cl. 8.

28. The importance of screening assays to the pharmaceutical industry was highlighted recently in the case of *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, 40 F.3d 1223 (Fed. Cir. 1994), involving the issue of inventorship of NIH scientists who assisted Burroughs Wellcome scientists in identifying AZT as a useful anti-HIV pharmaceutical through the NIH scientists' application of a screening assay designed to identify agents capable of inhibiting HIV infectivity. *Id.* at 1225-27. The court held that the Burroughs scientists had complete conception—a "definite and permanent idea"—of the invention for the use of AZT as a therapy for treating persons infected with HIV before the NIH scientists conducted the assay. *Id.* at 1230-31. The NIH scientists, the court reasoned, only confirmed the operability of the invention after the Burroughs Wellcome inventors had a complete conception. *Id.* at 1230. Thus, their acts were part of the reduction to practice inuring to the benefit of the Burroughs Wellcome inventors. *Id.* The court also held that a question of fact existed as to the inventorship of a patent drawn to a method of using AZT to increase T-lymphocytes in AIDS patients. *Id.* at 1231-32.

29. For an in-depth review of the case law regarding the research exemption in the United States see Feit and Hantman, *supra* note 18, and Bee, *supra* note 19.

30. 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).

31. 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391).

32. 29 F. Cas. at 1121.

33. 21 F. Cas. at 555.

34. *See* Hantman, *supra* note 18, at 620; Lauren C. Bruzzone, *The Research Exemption: A Proposal*, 21 AM. INTELL. PROP. L. ASS'N Q.J. 52, 56 (1993); Michel, *supra* note 15, at 372.

35. 3 WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 898, at 55, 56 (1890) (emphasis added).

36. *Id.*

37. 1 IVER P. COOPER, BIOTECHNOLOGY AND THE LAW, § 5A.12, at 5A-73-5A-74 (1992) ("Professor Robinson pointed out that the patented product may be intended for experimenters.").

38. These cases are of particular relevance as the Federal Circuit has announced that it is bound by that court's precedents. *See South Corporation v. United States*, 690 F.2d 1368, 215 U.S.P.Q. 657 (Fed. Cir. 1982) (*en banc*) (adopting as precedent the law of its predecessor courts, the Court of Customs and Patent Appeals and the Court of Claims).

39. *See Ordinance Eng'g Corp. v. United States*, 84 Ct. Cl. 1, 4 (1936), *cert. denied*, 302 U.S. 708 (1937) (excluding from accounting 7,425 illuminating shells allegedly built for experimental and ballistic purposes); *Chesterfield v. United States*, 159 F. Supp. 371, 375 (Ct. Cl. 1958) (holding that the use of 3,679 pounds of a patented alloy was experimental since a "portion" of the alloy was used for experimental purposes, and "there [was] no evidence that the remainder was used other than experimentally"); *Finney v. United States*, 178 U.S.P.Q. 235 (Ct. Cl. 1973) (finding that the one-time use of patented glove by NASA in an experiment was covered by "the doctrine of *de minimis non curat lex*" (the law is not concerned with trifles)).

40. In *Douglas v. United States*, 181 U.S.P.Q. 170 (Ct. Cl. 1974), *aff'd*, 510 F.2d 364, *cert. denied*, 423 U.S. 827 (1975), the court found that the experimental use defense did not apply where the United States bought six British-made aircraft and replacement engines and used them for a four-year period, stating:

> [I]n none of the cases . . . has the defense been permitted where there was a pattern of systematic exploitation, extending over a prolonged period, of a plurality of the accused devices for the purpose of furthering the legitimate interest of the user . . . . [E]ach use was in keeping with the legitimate business of the using agency and served a valuable governmental and public purpose.

Id. at 177. Similar conclusions were reached by the court in *Pitcairn v. United States*, 547 F.2d 1106, 1125-26 (Ct. Cl. 1976) (finding that "tests, demonstrations, and experiments" using infringing aircraft were "intended uses" of such aircraft and are "in keeping with the legitimate business" of the government), *cert. denied*, 434 U.S. 1051 (1978), and *Deuterium Corp. v. United States*, 19 Ct. Cl. 624, 632 (1990) (finding that the Department of Energy's role in the development of a pilot plant was within the department's legitimate

business of conducting "energy experiments and demonstration projects").

41. 181 U.S.P.Q. at 177.

42. 13 F. Supp. 697 (D. Colo. 1935), *rev'd on other grounds*, 87 F.2d 35 (10th Cir. 1936).

43. *Id.* at 700.

44. *Id.* at 713.

45. *Id.* at 703.

46. *Id.* at 713.

47. 733 F.2d 858 (Fed. Cir. 1984).

48. *Id.* at 863 ("Bolar's intended 'experimental' use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry. . . Bolar may have intended to perform 'experiments,' but unlicensed experiments *with a view to the adaptation of the patented invention to the experimenter's business* is a violation of the rights of the patentee to exclude others from using his patented invention.") (emphasis added). The provisions of the Act, codified at 35 U.S.C. § 271(e), negated the specific holding of *Roche Products* by providing that it shall not be an act of infringement to practice a patented invention "solely for uses reasonably related to the development and submission of information" to the FDA. The Claims Court contends that the Act has no effect on the broader holding of *Roche Products. Deuterium Corp. v. United States*, 19 Cl. Ct. 624, 632 n.14 (1990) ("Although [passage of the Drug Price Act] changed that narrow application of the doctrine affecting reporting requirements for federal drug laws, Congress did not disturb the Federal Circuit's parameters of the experimental use exception."). However, the validity of this position is unclear. *See Eli Lilly and Co. v. Medtronic Inc.*, 872 F.2d 402, 405, 406 (Fed. Cir. 1989) (noting *in dictum* that the Act overruled Roche "in all of its ramifications"), *aff'd on other grounds*, 496 U.S. 661 (1990). Nevertheless, according to the Federal Circuit's "prior panel rule," in a case not involving § 271(e)(1), *Pitcairn* is still binding precedent as the panel in *Eli Lilly* cannot effectively overrule an earlier panel's holding. *Capitol Elec., Inc. v. United States*, 729 F.2d 743, 746 (Fed. Cir. 1984).

49. This situation is more common than one might suppose. For example, the litigation between Ligand Pharmaceuticals and the La Jolle Cancer Research Foundation involved patents covering aspects of retinoid technology utilized in the discovery and characterization of retinoid compounds—similar to the patented assay hypothetical. These patents had been developed by funds from government grants and the La Jolla Cancer Research Foundation apparently practiced the patented technology in furtherance of research also funded by a federal grant. However, this litigation settled without the raising of any of the defenses discussed in the text. *See, e.g., Ligand and ALRT Settle Patent Infringement Suit Against La Jolla Cancer Research Foundation, SelectRA and SRI*, CANADA NEWSWIRE LTD. August 23, 1995 (available on LEXIS).

50. Although no specific support could be found for this proposition, the authors were told informally by attorneys representing such a federal agency that absent execution of documents authorizing the researcher to act on the behalf of the federal government, no license would exist.

51. 28 U.S.C. §1498(a) provides that:

> Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims...

52. Note: the express authorization of the federal agency may not be required if the awarding of a grant constitutes authority to act on behalf of the federal agency, if only in pursuing the research activities envisioned by the grant.

53. *See* Hantman, *supra* note, at 620-21.

54. 35 U.S.C. § 271 (1988).

55. *See* H.R. REP. NO. 857, 98th Cong., 2d Sess., pt. 1, at 16-18 (1984), *reprinted in* 1984 U.S.S.C.A.N. 2647, 2686.

56. *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 406 (Fed. Cir. 1989), *aff'd on other grounds*, 496 U.S. 661 (1990).

57. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670 (1990).

58. *Id.* at 670-71.

59. *See Intermedics, Inc. v. Ventritex*, 775 F. Supp. 1269 (N.D. Cal. 1991), *aff'd*, 991 F.2d 808 (Fed. Cir. 1993); *Chartex Int'l PLC v. M.D. Personal Prods. Corp.*, 5 F.3d 1505 (Fed. Cir. 1993) (unpublished), *available in* 1993 U.S. App. LEXIS 20560; *Telectronics Pacing Systems Inc. v. Ventritex Inc.*, 982 F.2d 1520 (Fed. Cir. 1992).

60. *Intermedics*, 775 F. Supp. at 1281; *Chartex*, 1993 U.S. App. LEXIS 20560, at *4; *Telectronics*, 982 F.2d at 1523.

61. *Intermedics*, 775 F. Supp. at 1281; *Chartex*, 1993 U.S. App. LEXIS 20560, at *4; *Telectronics*, 982 F.2d at 1523. On similar facts, each of these three cases held that the particular unlicensed use of the patented invention was not infringement under either § 271(a) or (e)(1). *Intermedics*, 775 F. Supp. at 1289; *Chartex*, 1993 U.S. App. LEXIS 20560, at *13; *Telectronics*, 982 F.2d at 1525.

62. *Scripps Clinic and Research Found. v. Genentech Inc.*, 666 F. Supp 1379, 1396 (N.D. Cal. 1987), *aff'd*, 927 F.2d 1565 (Fed. Cir. 1991). The court appeared to read a "purpose" requirement into § 271(e)(1) by stating that:

> The statute's meaning is clear: the use of a patented invention is protected so long as that use is solely for purposes reasonably related to meeting the reporting requirements of federal drug laws. Therefore, to establish entitlement to the statutory exemption, Genentech must demonstrate that it made and used... Factor VIII:C preparations solely for the purpose of meeting FDA reporting requirements.

Id.

63. In a footnote in the *Telectronics* opinion, the Federal Circuit observes that the magistrate's opinion in *Intermedics* was a "carefully reasoned and exhaustive analysis of this point." *Telectronics*, 982 F.2d at 1525 n.5.

64. *Intermedics*, 775 F. Supp. at 1269, 1277-80.

65. *Id.* at 1281.

66. *Id.* at 1281-82 ("Because we have determined that our inquiry should be confined to 'uses' that would be infringing but for the exemption, these collateral, noninfringing, activities are not relevant.").

67. *Id.* The court went to great lengths in questioning whether demonstrations at trade shows were "uses" for the purposes of § 271(a). *Id.* at 1285-89. The court found that absent the "totality of the circumstances" indicating that substantial advances had been made at the trade show towards an actual sale of a device, the mere demonstration at a trade show was not an actionable "use" under § 271(a). *Id.* at 1286-87. Nevertheless, the court found that a trade show demonstration, even if constituting a "use" cognizable under § 271(a), was protected under § 271(e)(1). *Id.* at 1289.

68. For example, in *Chartex*, the Federal Circuit found that a doctor's personal use of a female condom constituted a study aimed at determining suitability for FDA studies covered by the exemption. *Chartex*, 1993 U.S. APP LEXIS 20560, at *11. The court also found that uses of the device in consumer focus groups, color tests and interviews were also covered by the exemption. *Id.* at *9. It is not clear whether the court considered these activities to be non-infringing "uses," or infringing uses subject to the exemption.

In *Telectronics*, the court found that demonstrations of the defendant's defibrillators to medical conference attendees, some of whom were nonphysicians, constituted an exempt use reasonably related to FDA approval as device sponsors are responsible for selecting qualified investigators and providing information to them. *Intermedics,* 982 F.2d at 1523. The remaining complained of uses—presenting clinical data at a cardiology conference; reporting clinical trial progress to investors, analysts and journalists; and describing clinical trial results in a private fund-raising memorandum—were found to be merely dissemination of data and not infringing uses. *Id.* at 1523-24.

69. *Eli Lilly & Co. v. Medtronic Inc.*, 496 U.S. 661, 665 (1990). *See also* 35 U.S.C. § 100(a) (1988) (providing that "[t]he term 'invention' means invention or discovery").

70. *See Eli Lilly,* 496 U.S. at 674.

71. *See, e.g., Deuterium Corp. v. United States*, 19 Cl. Ct. 624 (1990).

72. *See, e.g.,* Patents Act, 1977, ch. 37 (Eng.); Patents Act, 1978, art. 69, § 1 (Jap.);, *reprinted in* 6 EHS Law Bulletin Series (Eibun-Horei-Sha, Inc., ed., 1978); WORLD INTELLECTUAL PROPERTY GUIDEBOOK: FEDERAL REPUBLIC OF GERMANY 2-139, (Bern and Rüster ed.,

1991) (noting that German law protects the experimental use of patented inventions under § 11 No. 1 PatG (1981)).

73. *See, e.g.,* Patent House Report, *supra* note 22, at 69. This sentiment was alluded to by Carlos J. Moorhead in his opposition to the proposed statutory research exemption, where he stated that:

> The stated purpose of this title is to protect university research activity. I fail to understand what universities are being protected from. There has never been a case, to my knowledge, where a university has been sued for patent infringement for carrying on research on a patented invention. If the existing patent law is harming universities or interfering with their research, I believe they should come forward and explain the nature of the problem.

Id. at 69.

74. *See, e.g., Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269 (N.D. Cal. 1991), *aff'd*, 991 F.2d 808 (Fed. Cir. 1993); *Chartex Int'l PLC v. M.D. Personal Prods. Corp.*, 5 F.3d 1505 (Fed Cir. 1993) (unpublished), *available in* 1993 U.S. App. LEXIS 20560; *Telectronics Pacing Sys., Inc. v. Ventritex Inc.*, 982 F.2d 1520 (Fed. Cir. 1992).

75. *See* Feit, *supra* note 18, at 821.

76. *In re* Reclosable Plastic Bags, 192 U.S.P.Q. 670, 679 (U.S. Int'l Trade Comm. 1977). The "first sale" or "patent exhaustion" doctrine holds that the first authorized sale of a patented product "exhausts" the patent control by the patentee. *Id.* The patent confers no rights upon the patentee to attempt to control the product after it has been sold. *Id.; but see Mallinckrodt Inc. v. Medipart Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992) (holding that if the sale of a patented device was validly conditioned to include certain use restrictions, then violation of the use restrictions is actionable as a patent infringement if the restriction is within the scope of patent).

Use of Bailment in Transferring Technology from a University

P. Martin Simpson, Jr.*

Technology transfer from a university is accomplished in many ways, formal and informal. Publication and professional interactions are two of the informal methods; however, an increasingly traveled route over the last two decades is formal licensing. Most licensing is of patents or of copyrights. Yet during this same time period, technological change has increased the importance of access to tangible personal property as a further means of technology transfer. In the 1980's biotechnology companies solved the tangible material transfer problem through use of the ancient legal tool of bailment, where possession, but not title, of tangible personal property is transferred for a limited purpose and duration. Then universities started utilizing bailment to accomplish transfer of new technology as well. Now bailment is a tool available for use with technology originating at national laboratories run by universities.

Bailment is a useful technology transfer tool in two particular situations. One case arises out of the explosive growth of biotechnology over the last two decades, and the other case is a mechanism to accomplish technology transfer through the use of tangible research products generally. In many instances over the past two decades the traditional patent system has not been

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able to provide practical or cost-effective protection for a biotechnology invention, if any protection was available at all. Today biotechnology patents are still an evolving area of the law, with court interpretations providing ever narrowing patent protection.

For example, the line of cases of *Amgen, Inc. v Chugai Pharm. Co.*, 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991) (claimed specific biological activity modified by "about" does not satisfy the definiteness requirement of 35 U.S.C. 112, and simultaneous conception and reduction to practice is applied), *Fiers v Revel*, 984 F.2d 1164, 25 U.S.P.Q.2d 1601 (Fed. Cir. 1993) (one does not have a DNA-based invention until one has the DNA sequence), and *The Regents of the University of California v Eli Lilly and Co.*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997) (first successful cloning of an important animal hormone in a bacterium using recombinant DNA technology revealing the DNA for making rat insulin provides an inadequate description for a genus claim to vertebrate insulin under 35 U.S.C. 112) apparently take a narrow view of when an inventor is in possession of a DNA-based invention and what the available breadth of patent protection is, even for ground-breaking, early research. Additionally, some early developments of biotechnology, such as hybridomas, became increasingly subject to U.S. Patent and Trademark Office ("PTO") "obviousness" rejections to limit eventual patent coverage.

Increasingly, the early uncertainty in the biotechnology community concerning how patent law would be applied to DNA-based inventions has been converted into concern for the narrowness of court recognized claim coverage after many years of proceedings in the PTO and in court. Uncertainty and narrow patent protection undercut the ability of a company to justify the expense and opportunity choice of bringing a biotechnology invention to the market. Many biotechnology inventions require hundreds of millions of dollars to be commercialized through the FDA licensing process. The lack of predictability of the patent system is illustrated by DNA-based

inventions from the 1980's still awaiting the protection of an issued patent.

In the 1980's, the uncertainty over patent protection available after many years of patent prosecution led to employment of an alternate form of protection uniquely suited to the new field of biotechnology. That protection is the bailment contract. In biotechnology, an invention frequently is embodied in biological material and in some cases cannot effectively be separated from or practiced without the tangible embodiment. Even where a biological material can be remade without the original biological material, the new biological material may not have exactly the favorable qualities of the old material and may take significant time, effort, and expense to recreate. Hence, the well-developed law of bailment became a mainstay of biotechnology technology transfer between companies in the 1980's. Universities rapidly followed suit to take advantage of a rapid, cost-effective, and predictable tool in the new technology. In doing so, universities did not give up their traditional devotion to academic publication of research or the preference for patent protection for inventions where appropriate. Academic researchers remain subject to the "publish or perish" imperative of academic advancement.

Turning to the law of bailment, a definition is as follows:

> A bailment may be defined as the rightful possession of goods by one who is not the owner. Bailment has also been defined "as a delivery of personality for some particular purpose, or on mere deposit, upon a contract, express or implied, that after the purpose has been fulfilled it shall be redelivered to the person who delivered it, or otherwise dealt with according to his directions, or kept until he reclaims it, as the case may be." (*A Treatise on the Law of Contracts*, 3rd ed., by Samuel Williston Vol. 9, Ch. 35, Sec. 1030 (1967)) ("Williston")

Note that the bailment definition in an exhaustive work such as Williston does not include a requirement that the bailor be the owner of the property bailed. In most cases the bailor is the

owner; hence, a reference in a less complete treatment may appear to make bailor and owner synonymous.

Bailment has a long history to make the protection offered predictable—a requirement for greatly increasing the likelihood of a successful transfer of technology. The fundamental and historic nature of bailment has been expressed as follows:

> It is difficult to think of an even moderately organized economic and legal society where problems incidental to bailment transactions would not arise. ... The modern law of bailment has borrowed heavily from the Roman law, and many of the doctrines of the law of bailments today are directly traceable to Roman sources. In the great case of *Coggs v. Bernard* (2 Ld. Raym. (K. B.) 909 (1704)), a simple matter involving the liability of one who gratuitously undertook to transfer certain brandies from one cellar to another and by his negligence damaged them, Lord Holt in 1703, relying upon the Thirteenth Century writer, Bracton, imported into the common law great portions of the Roman law of bailments ... (*Brown on Personal Property*, 2nd ed., by Ray Andrews Brown Ch. X, Sec. 73 (1936)) ("Brown")(Citation added from footnote)

Use of bailment to protect inventions has a long history as well. Also, protecting an invention by use of bailment does not rely upon maintaining a trade secret, an important consideration for university and national laboratory alike. A university can bail tangible personal property embodying the invention and still publish a description of an invention without necessarily destroying the contractual protections in a bailment. The California Supreme Court has considered bailment protection of inventions as follows:

> ... plaintiff is not required to rely upon the secrecy of its invention. We have here a relationship created by contract where the manufacturer took into his custody certain patterns created by the inventor for the purpose of manufacturing castings from them for the inventor. ... Where a bailee of an article has accepted it under definite terms to hold it and use it for the benefit of the bailor, a confidence has been reposed which should remain inviolate. The mere

> fact that the ingenious principle materialized in the thing bailed may be known to all the world would not depreciate the sanctity of the contract between the bailor and the bailee. (*Hollywood Motion Picture Equipment Co., Ltd. v. Furer* (1940) 105 P.2d 299, 16 Cal.2d. 184 at 188) ("Hollywood")

Also, inventions have a distinct legal existence apart from patent rights. In California the existence, ownership, and transfer of rights in inventions are recognized as follows:

> The inventor or proprietor of any invention or design, with or without delineation, or other graphical representation, has an exclusive ownership therein, and in the representation or expression thereof, which continues so long as the invention or design and the representations or expressions thereof made by him remain in his possession. (Cal. Civ. Code Sec. 980(b))

> The owner of any invention or design, or any representation or expression thereof, may transfer his property in the same. (Cal. Civ. Code Sec. 982(b))

> If the owner of an invention or design does not make it public, any other person subsequently and originally producing the same thing has the same right therein as the prior inventor, which is exclusive to the same extent against all persons except the prior inventor, or those claiming under him. (Cal. Civ. Code Sec. 984)

It is worth noting that the original codification of this invention ownership concept occurred in California in 1872. The distinction between inventions and forms of enforceable protection such as patents was further drawn as follows:

> We are dealing here, however, with the inventions before issuance of patent. Under the common law, which has not been changed by statute, an inventor has a natural but not an exclusive right to use and sell his invention independent of any rights conferred by the issuance of a patent. The only effect of a patent is to confer upon the patentee the right to exclude others from the use thereof. (*Summerhays v Scheu*

> (1936) 52 P.2d 512, 10 Cal.App.2d 574 at 576) ("Summerhays")

The U.S. Supreme Court has considered inventors' rights in the federal context and found the federal government to be no different than private parties:

> The government has no more power to appropriate a man's property invested in a patent than it has to take his property invested in real estate; nor does the mere fact that an inventor is at the time of his invention in the employ of the government transfer to it any title to, or interest in it. An employee, performing all the duties assigned to him in his department of service, may exercise his inventive faculties in any direction he chooses, with the assurance that whatever invention he may thus conceive and perfect is his individual property. There is no difference between the government and any other employer in this respect. (*Solomons v United States*, 137 U.S. 342, 11 S. Ct. 88, 34 L. ed. 667 at 669 (1890)) ("Solomons")

Thus, as a matter of law, the federal government is bound by the same common law of invention and patent rights as exists for all others in the society, absent intervening statutory changes since 1890.

Federal preemption does not appear to have destroyed common law (and its codifications) protections for inventions. Of the forms of intellectual property protection (patents, copyrights, trademarks, and trade secrets) available, the U.S. Supreme Court held that federal preemption in patents did not destroy state contract law protection, in that case trade secret:

> Our conclusion that patent law does not pre-empt trade secret law is in accord with prior cases of this Court. ... *Trade secret law and patent law have co-existed in this country for over one hundred years*. Each has its particular role to play, and the operation of one does not take away from the need for the other. Trade secret law encourages the development and exploitation of those items of lesser or different invention that might be accorded protection under the patent laws, but which items still have an important part

> to play in the technological and scientific advancement of the Nation. Trade secret law *promotes the sharing of knowledge*, and the efficient operation of industry; it permits the individual inventor to reap the reward of his labor *by contracting with a company* large enough to develop and exploit it. (*Kewanee Oil Co. v Bicron Corp.*, 416 U.S. 470, 94 S. Ct. 1879, 40 L. Ed. 315 (1974) at 492-493) ("Kewanee Oil") (emphasis added)

In 1980, the Congress passed P.L. 96-517 directing the policy choice for nonprofits and small businesses engaged in "the performance of experimental, developmental, or research funded in whole or in part by the Federal Government" (35 U.S.C. 201(b)) that:

> Each nonprofit organization or small business firm may, within a reasonable time after disclosure as required by paragraph (c)(1) of this section, *elect to retain title to any subject invention* ...
> (35 U.S.C. 202(a)) (emphasis added to P.L. 96-517 text)
>
> ... that the Federal Government *may receive title* to any subject invention in which the Contractor does not elect to retain rights or fails to elect rights within such time. ...
> (35 U.S.C. 202(c)(2)) (emphasis added to P.L. 96-517 text)
>
> ... a contractor electing rights *in a subject invention agrees* to file *a* patent application(s) *prior to any statutory bar date* (within reasonable times) ... and that the Federal Government may receive title to any subject inventions ... in which the contractor has not filed patent applications on the subject inventions within such times. (35 U.S.C. 202(c)(3)) (emphasis for text added by P.L. 98-620 and parenthesis for material deleted then)
>
> ... with respect to a funding agreement for the operation of a Government-owned-contractor-operated facility, requirements (i) that after payment of patenting costs, licensing costs, payments to inventors, and other expenses incidental to the administration of subject inventions, 100 percent of the *balance of any royalties or income* earned and retained by the contractor during any fiscal year ... *shall be used by the contractor* for scientific research, development,

> and education consistent with the research and development mission and objectives of the facility ... (35 U.S.C. 202(c)(7)(E)) (emphasis added)
>
> This chapter shall take *precedence over any other Act* which would require a disposition of rights *in subject inventions* of small business firms or nonprofit organizations contractors in a manner that is inconsistent with this chapter ... The Act creating this chapter shall be construed *to take precedence over any future Act* unless that Act specifically cites this Act and provides that it shall take precedence over this Act. (35 U.S.C. 210(a)) (emphasis added to P.L. 96-517 text)

The above provisions are fundamentally different from the "shall vest" language mandating title in the federal government in 42 U.S.C. 2182 related to atomic energy and 42 U.S.C. 5908 related to nonnuclear energy. The P.L. 96-517 statutory presumption is a return to invention title being "retained" by the inventor or his/her employer instead of by the federal government. Thus the basic common law understandings in invention rights are operative to the extent of P.L. 96-517 election. Where the contractor does not file for patent rights as the form of protection for an invention, the federal government "may receive title." There is no mandate for the federal government to exercise this right.

Moreover the protections built into P.L. 96-517 are phrased predominantly in terms of the invention, especially: the paid-up license to the federal government at 35 U.S.C. 202(c)(4), the prohibition on a nonprofit assigning title at 35 U.S.C. 202(c)(7)(A), the requirement that net royalties "earned ... with respect to subject inventions ... be utilized for the support of scientific research or education" at 35 U.S.C. 202(c)(7)(C), the small business preference in nonprofit licensing at 35 U.S.C. 202(c)(7)(D), retention of rights by the inventor at 35 U.S.C. 202(d), assignment to the nonprofit or small business of an undivided interest "when a Federal employee is a coinventor of any invention" at 35 U.S.C. 202(e), a bar to a federal agency requiring the licensing of background inventions at 35 U.S.C. 202 (f), all of the march-in-rights at 35 U.S.C. 203, the

preference for U.S. industry at 35 U.S.C. 204, the precedence of P.L. 96-517 over other inconsistent laws at 35 U.S.C. 210(a), and education awardee protection at 35 U.S.C. 212. The phrasing of P.L. 96-517 is predominantly in terms of invention rights—not patent rights—and the presumptions are in favor of contractor title to inventions where the common law applies.

The P.L. 98-620 amendments of 1984 to P.L. 96-517 focused on "minor improvements ... to make P.L. 96-517 work even better" for nonprofits and on expansion of such rights to the federal laboratories operated by nonprofits and small businesses. Senate Report No. 98-662 stated:

> After nearly four years of experience with P.L. 96-517, it is clear that the Act is accomplishing what it was intended to do. All of the major research universities appear to agree that the assurance of clear title to Government-funded inventions produced by the Act has led directly to increased patent licensing. Even more important, this assurance has been a major factor in allowing increased business support and collaboration in university research. Universities can negotiate with businesses and reach agreements over who will have what rights to inventions that come from joint efforts when the universities own the basic patents. Experience has shown, however, that some minor improvements are needed to make P.L. 96-517 work even better. ... (at page 2)
>
> The bill has particular value to the universities that run Federally-owned research facilities under contract to the Government *by ensuring that these universities will have the same rights to own inventions that they have under other Federal funding agreements*. ... (at page 3) (emphasis added)
>
> S. 2171 repeals the P.L. 96-517 provision excepting inventions made by nonprofit organizations when operating Government-owned laboratory facilities. This provides for *uniform treatment of all domestic nonprofit organizations regardless of where they perform their Federally-funded work* and is particularly important to organizations that manage Department of Energy laboratories. (at page 8) (emphasis added)

The legislative history in P.L. 98-620 explicitly states that universities are to be given the "same rights to own inventions" arising out of federal laboratories they operate as is practiced on campuses under P.L. 96-517. Again, the statement is made in terms of invention ownership, not ownership of patent rights.

With regard to university practices, the Association of University Technology Managers ("AUTM") published its AUTM *Technology Transfer Practice Manual* in 1993, illustrating the practice of many universities. Part IV, Chapter 3.2 "Unpatented Tangible Property: Biological Materials" and its Supplementary Material "Biological Licensing" are relevant material. This material is also available at AUTM's web site in AUTM Publications: *Journal of the Association of University Technology Managers*, Volume IV, 1992, "Biotechnology Licensing," by Annie Yau-Young and Marilyn Ziemer. Comments on bailment are as follows:

> 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 patent are not involved, though 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 clause on product liability, diligence, etc. ... (at page 11)
>
> ... 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. ... (at pages 11 to 12)
>
> ... 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. (at page 12)

Many TRP [Tangible Research Property] materials are of interest to companies marketing biological materials to the research community. It, therefore, makes sense to routinely advise such companies of newly disclosed TRP. While research markets are typically much less in sales than pharmaceuticals, they can provide considerable financial return to universities and researchers for their research. Sometimes, the developers are interested in having a convenient source of supply that eliminates the need for growing their own materials for further work; a license to a research reagent marketer may provide for such supply. (at page 4)

In licensing TRP, the licensor's bargaining position may be weak if there are other, equivalent (or at least comparable) materials available from other researchers or universities. In such cases, the licensee does not acquire much protection for his application, but pays for the convenience of getting a largely existing material without having to produce it in-house, or for a better characterized material than others currently available, or perhaps for having TRP provided from a more prestigious laboratory. (at pages 4 to 5)

In the AUTM *Technology Transfer Practice Manual*, Part IX, Chapter 3.2, a 1991 republished article entitled "The Treatment of Tangible Personal Property in Conjunction with Licensing of Patented Biotechnology" reports the following:

... It cannot be doubted that biotechnology licensing involves consideration of tangible personal property matters to a greater extent than does other technology licensing. This is because of the present inability adequately to describe an invention in words and to reproduce readily that invention from the description using generally available materials. (at page 2)

Biotechnology licensing, like any other technology licensing, requires an accommodation to the needs of the parties. The licensee requires the transfer of sufficient tangible and intangible property to achieve the basic goal of practicing the claimed invention, usually for commercial purposes. On the

> other hand the licensor desires to confine the property transfer to that calculated to result in the licensee's meeting its contractual obligations and, failing so, to permit effective recovery of that property—both tangible and intangible. Achievement of these respective goals demands that the rights and duties regarding both form of property be fully addressed in the written agreement(s) memorializing the intentions of the parties. (at page 2)
>
> Another potential problem for the intellectual property holder who sells tangible personal property concerns the doctrine of implied license. If the only use of that tangible personal property is to practice a patented invention, the seller may be deemed to have granted the buyer a license to practice the intellectual property. (at page 3)
>
> The thesis of this paper, first presented orally at the American Intellectual Property Law Mid-Winter meeting in 1986, is that licensing of biotechnology inventions often entails the transfer of biological materials, tangible personal property, in addition to patent or trade secret rights, intangible personal property. ... The history of the law of bailments was also reviewed with the conclusion that this ancient form of tangible property transfer was legally, as well as functionally appropriate to biotechnology licensing. Subsequently the transfer of biological materials as a bailment has received widespread approval and use in the biotechnology community. (at page 18 following the text of the Article)

University of California policy is similar to the policies of most universities regarding licensing. Relevant policy statements are as follows:

> Tangible research products include a wide range of tangible property resulting from the conduct of research, as distinct from copyrightable expressions and patentable inventions. Tangible research products may confer a public benefit through commercial licensing and may include biological materials, such as cell lines and plasmids; chemical compounds; electrical schematic diagrams; mechanical design drawings; and more abstract products such as detailed descriptions or compilations of laboratory procedures, analytical methods, or other such "know-how." ... (Guidelines

on University-Industry Relations, Guideline 10: Tangible Research Products)

In the event that research results are to be licensed, the University prefers that they be patented or copyrighted when possible. When this is not practical, licensing of tangible research products consistent with these Guidelines is permissible. When the University licenses tangible research products, it is willing to restrict commercial availability of such materials, but such agreements must permit the University to retain the discretion to publish any results of research at any time and to disseminate the tangible materials for educational and research purposes. Such publication and dissemination rights are essential to an academic institution of education and research. (Guidelines on University-Industry Relations, Guideline 10: Tangible Research Products) (emphasis added)

It is the intent of the President of the University of California, in administering intellectual property rights for the public benefit, to encourage and assist members of the faculty, staff, and others associated with the University in the use of the patent system with respect to their discoveries and inventions in a manner that is equitable to all parties involved. ... They shall execute such declarations, assignments, or other documents as may be necessary in the course of invention evaluation, patent prosecntion, or protection of patent *or analogous property rights, to assure that title in such inventions* shall be held by the University ... (University of California Patent Policy, October 1, 1997 revision) (emphasis added)

The NIH has decided that contractor licensing of unpatented inventions is acceptable as follows:

... Typically, the Contractor's election not to file a patent application on an invention is an indication that the Contractor is not interested in *retaining domain over the invention.*

However, 'his is not necessarily the case with regard to *patentable biological materials,* which may frequently be *licensed for commercial use without patent protection.* The policy and procedures established by this notice are intended

to simplify: (1) reporting by Contractors of their intention to not file a patent application on the invention but to license the tangible biological materials; and (2) the non-election of title to these inventions by the Federal Government where certain terms and conditions are met.

... To ensure consistency with its public availability goals, ... PHS Grants Policy Statement requires that where the product of research developed with federal funding is a patentable, but unpatented, research product, the *terms of a license must be no more restrictive than they would have been if the product had been patented.* (NIH Procedures for Handling Non-Election of Title to Patentable Biological Materials, NIH Guide, Vol. 25, No. 16, May 17, 1996) ("PHS Guide") (emphasis added)

Bailment has been recognized as a technology transfer tool at national laboratories. With respect to the U.S. Department of Energy/University of California operating contracts for Lawrence Berkeley National Laboratory, Lawrence Livermore National Laboratory, and Los Alamos National Laboratory, relevant portions are as follows:

"Laboratory Biological Materials" means biological materials capable of replication or reproduction, such as plasmids, viruses, DNA molecules, RNA molecules, prokaryote or eukaryote cell lines, and the like or associated biological products made under this contract by Laboratory employees or through the use of Laboratory research facilities. (Art. XII, CL. 11, I(a)(5))

"Laboratory Tangible Research Product (TRP)" means tangible material results of research which (i) are provided to permit replication, reproduction, evaluation or confirmation of research effort, or to evaluate its potential commercial utility, (ii) are not materials generally commercially available, and (iii) were made under this contract by Laboratory employees or through the use of Laboratory research facilities. (Art. XII, CL. 11, I(a)(6))

"Bailment" means any agreement in which the University permits the commercial or non-commercial access and use of Laboratory Biological Materials or Laboratory TRP for a

> specified purpose of technology transfer or research and development, including without limitation evaluation, and without transferring ownership to the bailee. (Art. XII, CL. 11, I(a)(11))
>
> In pursuing the technology transfer mission, the University is empowered to conduct activities including, but not limited, to the following: identification and protection of Laboratory Intellectual Property, ... Bailments ... It is fully expected that the University shall use all of the mechanisms available to it to accomplish this technology transfer mission ... (Art. XII, CL. 11, I(b)(3))

Thus, universities now employ the ancient Roman tool of bailment as an effective means of technology transfer from campuses and national laboratories operated for the federal government. In particular, universities have found bailment provides a vehicle well suited to both a university environment and the demands of modern biotechnology. Educational institutions retain their essential characteristics that publication is an imperative and patent rights are a preferred medium of technology transfer. Bailment provides a complementary alternative for the technology transfer process where patents do not provide adequate protection.

Instructions for Contributors

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