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Editor's Preface

The 2001 *Journal of the Association of University Technology Managers* includes five original papers on various topics of interest to the AUTM membership. Two papers address legal issues—one from a Canadian perspective and one from a United States perspective. Despite focusing on Canadian or U.S. law, both papers raise issues of importance to technology transfer in all countries. Two papers report on data gathered by the authors regarding aspects of academic technology transfer practice—one on gap-funding programs and the other a more general discussion of best practices. The final paper presents some thoughts about an emerging issue for technology transfer—the impact of medical privacy and informed consent on licensing practice.

Edward Gates and Michael Rader, both of the Boston law firm, Wolf, Greenfield & Sacks, in their article, "Disentangling Inventorship," discuss the difficulties of making correct inventorship determinations and the importance of these decisions. The authors note that often the academic culture contributes to the complexity of ensuring that only "true" inventors are listed and that none are missed. Perhaps most helpful to practitioners are their suggestions of ways to improve the invention-disclosure process to avoid some of the common pitfalls. A sample disclosure form is included as an exhibit.

Bell Canada attorney Christopher Cates addresses student-created intellectual property and its treatment under Canadian law and under the varying policies of Canadian universities in "Legal Issues within the Intellectual Property Policies of Canadian Universities: Standing on the Shoulders of Giants." He sees significant legal issues posed by university policies that claim ownership of student intellectual property—especially if that ownership were ever contested. While the article is written strictly from a Canadian legal viewpoint, the questions raised and the recommendations proposed should cause those in other countries to look closely at their approaches.

The third article, "Gap Funding in the United States and Canada," by University of Wisconsin–Madison authors Philip Sobocinski and Steven Price, takes a look at several gap-funding programs in the United States and Canada. Although some institutions already have such programs, many

more are thinking about initiating them. They will find the experiences reported in this article to be helpful in making those programs effective.

"A Review of Best Practices in University Technology Licensing Offices," by Michael Allan of First Principles Inc., reports observations gleaned from a study conducted by his firm for the Japanese External Trade Organization. While this article may be a bit basic for long-term technology transfer professionals, it reinforces many of our intuitive conclusions about what works well.

The final article in this volume of the journal, by Richard Kordal of the University of Cincinnati and Joseph Fondacaro of Cincinnati's Children's Hospital Medical Center, considers the impact of medical privacy laws and human-subject consent requirements on technology transfer practice in "Technology Licensing Meets Medial Privacy: Coexistence or Collision Course?" Although patient data and tissue samples may be a commercially valuable resource, especially with increased interest in data mining, the ethical issues and legal complexities that face institutions seeking to capitalize on these resources are certainly daunting. This article introduces the reader to the issues and will, hopefully, lead to further dialog within the technology transfer community.

This is the last volume of the journal for which I will serve as editor. I thank these authors and those in past volumes for their contributions and hard work responding to the questions and suggestions of our able Editorial Advisory Board and our managing editor. The journal would not be possible without the careful input provided by the board. My special thanks go to our managing editor, Diane Hoffman, who makes the process work and on whom I rely for advice and counsel. I wish the next editor continued success.

— Joyce Brinton, Editor

Disentangling Inventorship

Edward R. Gates and Michael N. Rader

The determination of inventorship under United States patent law has been described by the courts as "one of the muddiest concepts in the muddy metaphysics of the patent law" [*Mueller Brass Co. v. Reading Indus. Inc.*, 352 F. Supp. 1357, 1372 (E.D. Pa. 1972)]. Disentangling the parameters underlying this muddiest of concepts is crucial to all those involved in research and development, particularly in the university setting.

The patent statute defines an inventor as one who "invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" [35 U.S.C. § 101]. This general definition, however, is of little practical help when determining who should be named as an inventor on a patent application. Often, many individuals may contribute to an invention, on many different levels—from providing funding or other resources, to offering overall direction, to designing laboratory experiments or prototypes, to carrying out the mechanics of those experiments, or physically building those prototypes.

Over time, the courts have attempted, with limited success, to provide a more user-friendly framework for applying the general definition of inventorship in the patent statute. In general, courts have held that conception of the invention—that is, the formulation in the inventor's mind of a "definite and permanent idea of the complete and operative invention, as it is...to be applied in practice"—is the touchstone of inventorship [*Burroughs Wellcome Co. v. Barr Labs Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994)].

When two or more individuals collaborate on an invention, the patent statute provides that they may apply for a patent jointly. To qualify as co-inventors, the two individuals need not make the same type or amount of

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contribution. The test is still whether each contributed to the conception of the invention, and the necessary level of participation is measured in terms of material contribution to at least one claim of the patent. [*Ethicon Inc. v. United States Surgical Corp.*, 135 F.3d 1456, 1460 (Fed. Cir. 1998)]. As discussed below, this standard can sometimes be problematic for a number of reasons. First and foremost, it makes a firm determination of inventorship at the time of application for patent impossible, since the claim scope may change during prosecution of the patent.

In the university setting, the determination of inventorship is further complicated by factors such as economic incentives for obtaining patents, political issues associated with inventorship, and the complex relationships between researchers, administrators, university technology managers, and patent attorneys (frequently from outside law firms). Yet these hurdles must be overcome to ensure patent validity—which, in turn, safeguards the research goals of the inventors, the reputation of the university, and the technology transfer office's noble purpose of leveraging intellectual property for the public benefit.

The Legal Significance of Correct Inventorship

Proper naming of inventors is one of the fundamental statutory requirements for a valid patent and should receive at least the same scrutiny as novelty, nonobviousness, or utility of the invention before an application is filed and throughout the application process. Failure to name an inventor (nonjoinder) or naming of an incorrect inventor (misjoinder) can invalidate a patent.

Nonfraudulent mistakes in inventorship can be corrected either during patent prosecution (indeed, as noted above, such correction may be necessitated by claim amendments, additions, and cancellations made during prosecution) or after issuance of the patent. In the latter case, such corrections may be made either by application to the Commissioner of the Patent Office or by way of judicial action. To correct inventorship, a showing must be made that the mistake was made without any deceptive intent.

Failing to name an inventor or naming one incorrectly, if committed with deceptive intent, can render a patent invalid. Additionally, failing to name an inventor can place into question the patent owner's ability to enforce the patent or to transfer rights in the patent to others.

Ethicon v. U.S. Surgical provides an illustrative example. In that case, one of the co-inventors was not named as an inventor on the patent. The default rule is that all co-inventors jointly possess undivided ownership of a patent, and, thus, each co-inventor ordinarily has the right to license others to practice the patent. Of course, where all co-inventors assign their rights, the assignee (for instance, a university) maintains exclusive ownership of the patent and possesses the sole right to grant licenses. (In most cases, university employees are under a duty to assign their patent rights to the university.)

In *Ethicon*, the patent owner, Ethicon, brought suit against U.S. Surgical for infringement. However, U.S. Surgical discovered a co-inventor who had not been named on the patent and successfully petitioned the court to have him added as an inventor (i.e., to correct inventorship). U.S. Surgical then obtained a license to the patent from this co-inventor. The court held that the license obtained by U.S. Surgical from the third-party co-inventor defeated the suit for patent infringement, since U.S. Surgical had obtained a legal right to practice the patent, and dismissed the case. The appeals court affirmed this determination.

In light of cases such as *Ethicon*, all those involved in the process of applying for and procuring a patent must take care to ensure that all of the correct inventors (and only the correct inventors) are named.

Pitfalls in the University Context

University technology managers face a number of significant obstacles to the proper naming of inventors. First, patentable ideas often stem from scholarly papers or articles, on which authors may be listed whose contributions do not meet the standards for inventorship under applicable patent law. Where the invention disclosure form lists as inventors all those who authored a particular paper, further investigation is necessary to determine which of the authors is properly an inventor, and, in some cases, whether there may be additional individuals not listed on the paper who should also be named as inventors (for instance, the patentable invention may include elements not disclosed in the paper).

Second, the university-research setting, by its very structure, has a tendency to facilitate over- or underinclusive inventorship listings on invention disclosure forms. On the overinclusive side, the authors have encountered two primary problematic scenarios. First, some university laboratories make it their practice to name every member of the research team as an

inventor, without inquiring into individual contributions to the subject matter of the patent application. Second, some supervisory personnel feel they should be named as inventors on every patent application stemming from research conducted in their laboratories—because they may have done earlier pioneering work or because they provide overall direction for new developments, bring in funding, or carry out other administrative duties that make research possible. The political climate in a laboratory or other research setting can sometimes make it intimidating for subordinates to challenge supervisory personnel in this regard.

For the reasons outlined above, both of these approaches can lead to difficulties, up to and including outright invalidation of the patent. Moreover, the same result can occur when potentially patentable developments are predicated on proprietary materials obtained from an outside individual and that individual should have been named as an inventor.

Additional problems are possible despite the best of intentions. In some cases, a senior research mentor may conceive of an invention, but lead more junior researchers to it in such a way that they believe they came up with the idea themselves. Although undoubtedly the hallmark of a good teacher, this approach can lead to bitter disputes over inventorship and can make it difficult or impossible for an objective determination of inventorship to be made down the road.

Finally, the job of correctly establishing inventorship is further complicated by economic considerations. Royalties from patent-licensing activities can provide a significant incentive for obtaining status as an inventor. With regard to the splitting of royalties, different universities and different laboratories often have divergent policies. At one extreme, some universities require that inventions be assigned to the university, with no royalties flowing to the inventors. Most universities, however, apportion licensing revenues in part to the university, but reserve portions for the laboratory and/or the department, as well as the inventors themselves. In a small number of cases, researchers in a particular laboratory or team share royalties without regard to who is ultimately named as an inventor on the patent.

In cases where royalties are awarded to inventors, but not to other members of the research team, competition to be named as an inventor can be fierce, and political battles may ensue. University technology managers typically seek to avoid such political wrangling to retain their objectivity and preserve their working relationships with all parties. In any case, the final word on inventorship is usually left up to the patent attorney prosecuting the application in the patent office. This individual will, more often than not, be an outside lawyer hired by the technology transfer office.

Throughout prosecution of the patent application, the patent attorney keeps tabs on the state of the claims and how they relate to the contributions made by various individuals. Before the patent issues, the attorney performs a final check to ensure that inventorship is correct. When the allowed claims differ significantly from those filed in the original application, addition or removal of inventors may be necessary. In many cases, however, the inventorship established at the time the patent application is initially drafted will remain consistent throughout prosecution. This will only be true, however, if the information available to the patent attorney responsible for drafting the application is sufficiently detailed and accurate.

Using the Invention Disclosure Form to Avoid Pitfalls

Access to information is the key to the patent attorney's ability to do his or her job well. As noted above, determining inventorship when drafting a patent application is no exception. To facilitate this determination, most technology transfer offices have developed invention disclosure forms, which are filled out by researchers seeking to have their developments patented. These forms generally request a summary of the invention, a suggested title, and a list of inventors. The forms may also request information about financial support for the work that led to the invention, potential for commercial exploitation of the invention, documentation of conception and reduction to practice of the invention, and other details. In some cases, existing invention disclosure forms create or exacerbate a number of problems.

From a review of the invention disclosure forms used by various research institutions, we identified what we regard as the best practices for avoiding the various pitfalls discussed above. (The review included forms from five leading research universities and three leading hospitals.) A discussion of these practices follows. The analysis should be read in conjunction with the Proposed Invention Disclosure Form at exhibit A.

Explain the Legal Landscape

One of the most prevalent reasons for over- or underinclusive lists of purported inventors is misunderstanding of the legal standards for inventorship under patent law. For instance, as noted above, in some cases the individuals filling out the invention disclosure form may assume that anyone named as an author or investigator on a scholarly paper should be included as an inventor.

To forestall at least some of these mistakes, the invention disclosure form should clearly set out the applicable legal standards for inventorship under patent law. It should also explain that the information provided on the form will not be dispositive with regard to the inventors listed on the application, and that, moreover, changes to the list of inventors may be made during prosecution of the patent if necessitated by adjustments in claim scope. The explanation should be placed prominently at the top of the page. (In some cases, the authors found invention disclosure forms with explanations attached on separate sheets, effectively creating a "small print" that probably goes unread most of the time.) An illustrative example is shown at section 1 of exhibit A.

Use a Term Other than *Inventor*

Some invention disclosure forms request a list of inventors. This designation can lead to confusion, because it gives the individual filling out the form the expectation that all those listed will indeed become inventors on the patent. Other invention disclosure forms use the term *investigators* rather than *inventors*. This is a better approach, but could still lead to confusion among academics who associate the title of investigator on scholarly papers with the title of inventor on patents. We suggest instead using the word *contributor*, or some similar, neutral term. An illustrative example is shown at section 4 of exhibit A.

Moreover, it is important to establish the contributions made by each individual, along with any written documentation of such contributions. The form should explicitly request such information to aid the patent attorney in determining inventorship at each step of the patent-prosecution process. Such written documentation will also help establish dates of invention.

Finally, the form should explicitly ask whether the potentially patentable developments were predicated on proprietary materials obtained from an outside individual, because, in some cases, that individual will have to be named as an inventor. While the final determination will be left to the discretion of the patent attorney applying the patent law of inventorship, the information must be gathered up-front.

Do Not Request Names of Supervisors, Laboratory Heads, or Department Chairs

Almost all invention disclosure forms request information about supervisors, laboratory heads, or department chairs. This practice invites problems by listing individuals on the form who may not have contributed materially to the conception of the invention. If the identity of the supervisory individual is relevant, he or she will be listed as a contributor.

To the extent information on supervisors is necessary for purposes other than determining inventorship, it should be requested on a separate sheet clearly labeled as being for administrative purposes only—not relevant to determining inventorship or some similar designation. The same is true of any sponsorships, funding sources, etc., that are relevant to the research in question. An illustrative example is shown at exhibit B.

Blame the Lawyers

The relationship between university technology managers and the university's scientists can sometimes be strained, especially when outside rules and regulations (such as the patent law definition of inventorship) are being imposed. To mitigate tension, it should be clear that the inventorship determination is being made not by the technology transfer office, but by the patent attorneys hired to prosecute patent applications for the university. This is a legal determination, which must be made correctly to ensure validity of the patent, and, in this one instance, it is okay to blame the lawyers. The invention disclosure form should clearly indicate that the patent attorneys are in charge of the inventorship determination, and contributors with questions should be directed to the attorneys rather than to the university technology managers.

Conclusion

This paper sets out some of the problems encountered by university technology managers and patent attorneys in determining inventorship in the

university context. It suggests some solutions to these problems through the use of an improved and streamlined invention disclosure form. This form, and the accompanying commentary in this paper, obviously do not represent an exhaustive solution to all possible problems, but they do address the most common issues to arise and provide a starting point for any further modifications that may be necessary.

Exhibit A
Sample Invention Disclosure Form

1. Explanation of Legal Standards for Inventorship under Patent Law

Under United States patent law, an inventor is one who makes a material contribution to the subject matter of at least one claim of the patent. Since the scope of the patent claims is not determined until the *end* of the patent-prosecution process, a definitive determination of inventorship is not possible when the process is initiated, for example, by filling out this form. Thus, this form does not request a list of inventors, for that would call for a legal determination and prediction. Rather, this form requests instead a list of those individuals who contributed materially to what you consider the novel and nonobvious aspects of the invention or development described herein. You should understand that the final determination of who to list as inventors, both on any patent application which is filed based on this invention disclosure and on any patent that ultimately issues, will be made by a patent attorney applying the legal standards of inventorship under United States patent law.

2. Title of Invention

_____

3. Detailed Description of Invention/Improvements over Prior Art

_____

_____

_____

_____

_____

(Please attach additional pages if necessary.)

4. Contributors

Our patent attorneys have asked that you provide the following information: A brief description of the contributions made by each contributor, along with citations to written documentation (e.g., lab notebooks) corroborating the date or approximate date those contributions were made.

The attorneys have also asked that you attach photocopies of all such written documentation to this form. Additional listings of contributors may be attached to this form if necessary.

Name/Address/Phone	Contributions to the Invention	Written Documentation
1.		
2.		

5. Use of Proprietary Materials

Please indicate below whether any aspect of the invention is predicated on, or was made possible by use of, proprietary materials obtained from an outside individual or institution.

(Please attach additional pages if necessary.)

Today's Date

Authors' Note: *The invention disclosure form may ask for additional important information, such as whether the invention has been disclosed, published, or offered for sale. However, because this sample form is directed solely to issues of contribution and inventorship, only questions pertaining to those issues are included here. See exhibit B for possible additional questions not relevant to inventorship.*

Exhibit B

Sample Invention Disclosure Form

(Administrative page, not relevant to inventorship)

1. Funding and Support

Please indicate below whether the invention was supported by any grants, gifts, or contracts, including award numbers, time periods, and other relevant details.

(Please attach additional pages if necessary.)

2. Supervisory/Departmental Information

Please indicate below the supervisor for this project, the departments within which the work was done, and any laboratories that participated.

(Please attach additional pages if necessary.)

3. Commercial Potential

Please indicate below whether the invention has commercial potential, including the possible uses and markets for the invention, who would use it and why, the current corporations and/or institutions that might have an interest, and any specific contacts you have in this regard.

(Please attach additional pages if necessary.)

Legal Issues within the Intellectual Property Policies of Canadian Universities: Standing on the Shoulders of Giants

Christopher R. Cates

Abstract

Several Canadian universities use their internal policies to claim some form of ownership or license right with respect to student-created intellectual property. These policies are examined from a contract and employment-law viewpoint to determine their efficacy. It is concluded that a university would have significant legal issues to overcome before successfully claiming ownership of intellectual property created by its students. Specific recommendations are presented that attempt to resolve these apparent difficulties.

Introduction

If I have seen further it is by standing on the shoulders of giants.

> —Sir Isaac Newton, in a letter to his colleague, Robert Hooke, dated February 5, 1676[1]

The quotation above was made by Sir Isaac Newton when commenting that he has been able to conclude more about the universe than those before him because he was working in the light of their already significant work and achievements. Of course, the phrase itself epitomizes the progressive nature of academic research. Newton based his phrase on a guest-book entry made by Bernard of Chartres dating back to 1130.[2] Academic research is progressive, and the accumulation of knowledge is essential.

Universities form a key, if not the most important, component of the academic research community of Canada. Canadian universities contribute through scholarship, literature, and inventions to the overall understanding of our universe. Rights granted by intellectual property protect these

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contributions. Intellectual property rights allow the university to safeguard knowledge to ensure that it is made available for the benefit of society. That goal, of course, is only a theoretical ideal. In actuality, whether or not the benefit of society is still a guiding principle, the intellectual property owned by universities has the potential for generating large amounts of revenue both now and in the future.

The university community is comprised of a diverse variety of people contributing to the academic knowledge in any institution. Postdoctoral students, graduate students, and undergraduate students are important players within the university community. Each contributes uniquely to the university community. Also, in the course of their relationships with the university machinery, students generate massive amounts of research, including valuable documentation and scholarly writings. Some universities, perhaps in response to the anticipated growth of potential intellectual property rights, have internal policies that attempt to control or regulate the creation of intellectual property by students within their communities.[3]

This paper intends to examine the presumptions inherent in, either correct or incorrect, university policies regarding ownership of intellectual property created by students. Specifically, where the policies of a university purport to convey ownership of intellectual property from its creator to the university, it will be examined as to whether such a transfer is effective. This paper suggests that, where a university purports to be the owner of the intellectual property created by its students, in some circumstances, such transfers are ineffective.

Also to be discussed is whether or not there are overriding policy rationales that would justify giving effect to university policies that would otherwise be unenforceable at law. Finally, recommendations will be made that will assist a university when protecting its interests should it decide to take intellectual property ownership away from its students. It should be noted that, while each university will likely enunciate its policies in a different fashion, the broad underlying concerns for all universities remain the same. The purpose of this paper is not to critique the actual policies of any one university, but rather to discuss what can be done by all universities to reduce the chance that intellectual property rights are mismanaged.

The Current Situation

Among Canadian universities, intellectual property policies are diverse. Thankfully, surveys of this area were completed in 1998,[4] and the results are interesting when examined from the perspective of intellectual property ownership. The research from Ketis, Rudolph, and Gravelle provides a backdrop for this paper's discussions. A very clear distinction can be observed from an examination of the university policies. This distinction provides a near-bright-line method of distinguishing the various forms of policies and analyzing them effectively. This distinction creates the following classes of university policies.

- *University asserts intellectual property ownership rights in the work of students.* The university asserts that intellectual property created by its students is owned by the university despite the university's lack of authorship/creation. This does not preclude an additional assertion of secondary rights by universities.
- *University asserts mandatory secondary rights in the work of students.* The university does not assert ownership rights with respect to the work of its students; however, it does assert other entitlements. These entitlements may include: a mandatory gratuitous license back to the university of any intellectual property, a compulsory royalty payment, or other form of long-terms right or compensation.[6]
- *University does not assert any intellectual property ownership rights in the work of students.* The university reaffirms that it does not have any ownership rights in the work of its students.

The following figures summarize Canadian university policies based on the respective distinctions defined above:[5]

The chart on the following page summarizes findings from the Ketis study as well as a recent *Statistics Canada Report*.[6] Because a portion of the chart related to the *Statistics Canada Report* summarizes the treatment of both students and other researchers (including staff), it is not an entirely accurate representation of student-ownership policies. In this regard, the *Statistics Canada Report* has a more comprehensive sample size, and, therefore, merits discussion generally as an excellent sampling of the policies applied by universities.

The Ketis study dealt more directly with the rights of students. As is evident by the chart above, there appears to be some parity with respect to the

Ownership of intellectual property and secondary rights	Ketis survey	Statistics Canada Report (includes staff and students, only where reporting is required)								Average
	Generally	Inventions	Software	Literary, artistic works	Educational materials	Industrial designs	Trademarks	Integrated circuit topographies	New plant varieties	
University owns intellectual property and secondary rights	50%	23%	20%	4%	17%	35%	45%	33%	40%	30%
Shared ownership (possible secondary rights)	44%	66%	61%	23%	31%	45%	50%	50%	36%	45%
Researchers owns intellectual property, university has no secondary rights	6%	11%	20%	73%	52%	20%	5%	17%	24%	25%
Number of institutions	19	44	41	26	29	20	22	24	25	

universities that claim and those that do not claim ownership of intellectual property created by students. If anything can be stated clearly it is that there is no clear consensus as to how the intellectual property ownership is treated by Canadian universities, which may be related to the fact that there is presently no uniform legislative regime regarding such policies in Canada.

The clearest distinction can be seen with respect to secondary rights retained by universities. Where a university claims ownership of the intellectual property in question, the university would necessarily retain all rights related to such ownership. Of interest, however, is the majority view (and near consensus with respect to the Ketis study[7]) of universities—that is, that the universities are entitled to retain secondary rights in the intellectual property. In almost all cases in the chart above, the minority situation is the one in which the researcher owns all of his or her intellectual property (and the university claims no secondary rights).

One should note that there is really limited benefit to owning underlying intellectual property where these secondary rights exist. To take secondary rights to an extreme situation, if there is a mandatory 95 percent royalty on gross proceeds of commercialization of intellectual property, then the owner really is just a 5 percent beneficiary of the gross proceeds, which would hardly justify the promotion and maintenance obligations of intellectual property ownership.[8]

What is of particular interest is where the university asserts either ownership or secondary rights in the intellectual property of its students. Such regimes are not in concert with the rights granted to creators by the intellectual property laws in Canada. The importance of this paper's discussion is evident given its potential impact not only on the ownership of intellectual property, but also in the way secondary rights are granted back to the university. As all rights are derived from title (including secondary rights), it is important to discuss the law that grants ownership of intellectual property to a given person.

Ownership of Intellectual Property

The key distinction that is intended to be illustrated by this paper is that the statutory intellectual property regime (and subsequent case law that follows) differs greatly from many of the policy regimes in place at universities under which student-created intellectual property is governed. In order to determine whether the policies correspond with the general state of the law, it is important to discuss the current state of the law for the ownership of both copyright and patents (the primary intellectual property classes discussed in this paper), although ownership of intellectual property is also important with respect to the many other kinds of property that may be created.

Creation and Ownership of Copyright

The author of a work protected by copyright is generally considered to have first ownership of copyright.[9] The fundamental principle of copyright law is that the ownership of copyright must be distinguished from, and necessarily may not follow ownership of, the tangible media embodying the work itself.[10] When you purchase a book at a retail bookstore, you obtain the text but you fail to obtain copyright interests in the underlying work. This is essential in order to allow the owner to reap the benefits of the copyright interest. Unless an author of a work makes a transfer in writing of the copyright in the work to another person, the author owns copyright in the work.[11]

This applies to freelancers; however, a different test applies to employees.[12] Where the author of a work is employed, and the work is made in the course of employment, the employer is the first owner of the copyright in the absence of any agreement to the contrary.[13] Without exploring all the possible permutations, the author generally owns the copyright unless the author is a business that is using an employee to create the protected work.[14]

Creation and Ownership of Patents

Only the inventor or the inventor's legal representatives may apply for and receive a patent.[15] The legal representatives include the inventor's heirs, executors, administrators, and those to whom the inventor has transferred rights. The inventor is not necessarily the first person to conceive of a given idea, but rather the first to conceive of it in sufficient detail so that it can be explained to another.[16] In the context of an employment relationship, the rights of an employee in any inventions are usually determined by the terms of their employment.[17]

Express terms dealing with the ownership of patent rights and interests are common in employment contracts.[18] Where there is no such term in the employment contract, the duties of the employee and the relationship of the employee with the employer are used to determine the appropriate nature of ownership. Where an employee is hired, for example, to conduct patentable research, an invention made in the course of employment would belong to the employer.[19] To hold otherwise would appear to be inconsistent with the duty of good faith that is owed to the employer.[20]

In contrast, an invention made by an employee while at work, however, not acting within the defined scope of his or her employment, would likely belong to the inventor rather than the employer. A representative case may assist in placing these issues in their relevant context.[21]

In the 1991 case of *Comstock Canada v. Electec Ltd.*,[22] the Trial Division of the federal court rendered a significant decision in respect of the principles governing ownership of patents for inventions made by employees. In *Comstock Canada*, it was asserted that the employee was the inventor rather than the named inventor and that, despite having been employed by Comstock as manager of its electrical department at the time of the invention, the employee owned the patented invention. The employer contended, *inter alia*, that if the employee had made the invention he would have done so in the course of employment and that he was in a fiduciary relationship with the employer.

The court recognized that the general principle regarding employees' inventions was established in 1825. The court warned that caution must be used when applying the principles.[23] In applying these principles, the court found that Hyde (the employee) had not been hired to invent, his invention was not within the scope of his employment nor was it part of his day-to-day duties.[24] Hyde did not owe a fiduciary duty to Comstock. Rather, Comstock, in the circumstances, breached a fiduciary duty owed to Hyde with respect to his inventions, because the making and perfection of the invention was never part of the work for which he was paid and employed.[25]

In the result, the court declared Hyde to be inventor of the subject matter and Comstock the owner, but also affirmed that the court has absolute discretion with respect to a dispute as to inventorship including a declaration of invalidity, a declaration of inventorship and ownership, or any other declaration it sees fit.[26] The holding from *Comstock Canada* was followed quite recently in Ontario by the *Techform Products Ltd. v. Wolda* case.[27]

Additional consideration has been made as to patent creation in the employment context. Excellent illustrative examples can be seen recently in the *Seanix Technology Inc. v. Ircha*[28] and *C.I. Covington Fund Inc. v. White et al.*[29] cases *inter alia*. In *Seanix*, it was held that *Comstock Canada* was appropriate to apply to an employer-employee relationship. Specifically, *Seanix* held that the mere fact of employment does not obligate an employee to transfer an invention to the employer; however, where it was the very work that the employee was paid to do, then the employer was the rightful owner of the invention. This is consistent with the previous position enunciated.

In *Covington*, the Ontario courts reached the same conclusion as in *Seanix*. In *Covington*, the court affirmed the common-law presumption that an employee is the owner of his or her invention unless there is an express contract to the contrary. However, it did conclude that, where the employee's role was to develop a technology, the employer could claim that it was a beneficial owner of the applicable technology.

To summarize, the rights of an employee in any inventions are governed by the nature of the employment relationship. The duties of the employee and the relationship of the employee with the employer are fundamental where there are no contractual terms dealing with intellectual property. The production of intellectual property must be in the job description of the employee (in the case of patents) in order for the company to claim ownership of the intellectual property. The issue remains, however, as to how intellectual property may be legally conveyed to another person.

Conveyance of Intellectual Property

Generally, there is only one way to convey intellectual property rights and that is through contract.[30] The most common agreements that convey

intellectual property are assignments and voluntary licenses. In the patent context, an inventor may assign rights to an invention and to any patent that may be granted or has already been granted. An assignment may occur prior to filing an application, during the prosecution of the application, or any time after the grant of the patent. An assignment may be partial or total and may be limited by any factor including territory, time, or nature of use.

The other option is a voluntary license. The voluntary license permits the licensee to do acts that it would not otherwise be able to do with respect to the patented invention. Again, like assignment, the license may be general or limited in some way. The number of permutations is endless. Finally, should a patentee abuse those rights, in certain circumstances, a party may apply to have the Commissioner of Patents require a compulsory license be granted.[31] To a very similar degree, similar conveyances are possible within the copyright sphere as well.[32]

The University Policy Problem

The problem that is evident when universities purport to own intellectual property created by their students may be viewed in two different yet equally valid ways.[33] The first point of view is that any given university does not possess the traditional indicia of intellectual property ownership as set out above. It has not authored the work, nor conceived of the invention. The university, consequently, would not otherwise have intellectual property rights in the invention but for the attendance of the student. Without executing a separate agreement with the student to license or assign that intellectual property to the university, the university cannot exercise any of the creator's rights such as registration of a patent or protection of a copyright.

The second point of view takes the position that the university student possesses all the indicia required for first ownership of intellectual property regardless of whether the university has arguably some (but not all) indicia of ownership. The university student is the creator/inventor in all situations. The student may be in an employment-type relationship or in a purely academic relationship. The student may also be utilizing facilities that were university provided (through tuition fees). The key issue, however, is that of creation. The university still did not conceive the ideas or expression; the student alone does. Regardless of the university inputs (that were paid for partly through tuition), the university has done nothing original or

innovative. Therefore, the student is the proper owner of the intellectual property created.

Both points of view, which are equally valid (and in fact are magnified when viewed together), suggest that the university claiming first ownership of intellectual property is doing so in disagreement with the law governing ownership of intellectual property. In order for a university to gain ownership of student-created intellectual property, it is suggested that there would have to be some explanation other than first principles because traditional intellectual property law would not grant the university any rights in the work of the students.

There are two potential arguments regarding the vesting of student-created intellectual property in universities. A university may claim that *(a)* the student is in an employment relationship with the university or *(b)* that the student has actually accepted contractual terms that purport to transfer the intellectual property to the university. These two positions may be broadly defined as the *employment camp* and the *contract camp* respectively. Each will be discussed in turn.

The Employment Camp

The employment camp can best be applied to the graduate students who receive university stipends, those undergraduate students who are employed as research or teaching assistants, or those graduate or undergraduate students receiving some kind of scholarship. The belief is that, by paying the student for his or her time, the university creates an employment relationship that entitles the university to the ownership of that student's work product. Further, it may be argued that secondary rights are granted as part of the employment relationship. This position, however, is relatively weak given the generally accepted tests for an employment relationship. These tests, as will be illustrated, once applied to undergraduate and graduate students, will show that it is most probable that university students will not be found to be in an employment relationship with the university.

Traditionally, there have been three tests for employment status that are interrelated: the control test, the four-fold test, and the organizational test (also known as the specified-result test).[34] In addition, there are other factors that contribute to the discussion, namely, the classification applied by the parties themselves and the internal payroll practices.[35] Each will be

discussed in turn. The current common-law tests can be seen as a hybrid of the three traditional tests with persuasive weight given to the parties' classification and payroll practices.[36]

Under the control test, there were four traditional indicia of a contract of service. These four indicia were:

- the employer's power of selection of the servant;
- payment of wages or other remuneration;
- the employer's right to control the method of doing the work; and
- the employer's right to suspend or dismiss the employee.[37]

Of the four traditional indicia, the most important was held to be the third, the employer's right to control the method of doing the work.[38] Control of the work includes not only control of what work is to be done but also how the job is performed.[39] This test, however, fails to operate properly where there is a highly skilled or professional employee. Control is generally inadequate as a major indicator of employment status because these kinds of workers are granted a high level of autonomy because of the high level at which they work or the independent nature of their work (e.g., lawyers, researchers, etc.) This primary deficiency was addressed in the four-fold test.

The four-fold test was first enunciated in *Montreal v. Montreal Locomotive Works Ltd.*[40] The case suggested *inter alia* that, where the control test was inadequate by itself, the courts should consider:

- control;
- ownership of tools or job-related paraphernalia;
- chance of profit; and
- risk of loss.[41]

The Privy Council emphasized in *Montreal* that all elements of the relationship would be considered and indicated that a crucial question to ask when deciding the nature of the relationship is: "Whose business is it? Or, in other words, by asking whether the party is carrying on the business, in the sense of carrying it on for himself or on his own behalf and not merely for a superior."[42] Therefore, the four-fold test would appear to extend the existing control test, but not replace it, as the definitive indication of the employment relationship.[43] The four-fold test is more robust than the control test because it incorporates control and is more explicit than the prior tests and, therefore, is more easily applied.

The organizational test has many different names and is often called the specified-result, integration, or dependency test.[44] This test extends the four-fold test's concept of carrying on business in your own behalf and looks at the level of integration of the worker into the business of the employer. If a worker is economically dependent on one company or if the worker's activities are essential to business, the worker will be viewed as a dependent contractor, which is equivalent to an employee.[45] The organizational test is almost always treated as a contributing factor to the court's classification of a worker's status.[46] The specified-result test is a reworking of the organizational and control test by stating that the completion of a specified service or result without freedom to control the means of doing such work would tend to indicate an employment relationship.[47]

It can be stated from the previous employment-law authorities that the entire employment relationship must be examined to determine the type of classification that should be applied. This includes the way in which the parties themselves view their relationship. The parties' label of their situation, whether oral or in a written contract, will not be conclusive as it is the true relationship that is examined.[48] Where a working situation's classification is ambiguous, the label placed on the relationship may be persuasive.[49]

Of course, this premise only extends to bilateral labels but not significantly to a unilateral label.[50] References to a worker as an employee in memos or academic writings may be helpful to a court determining the true nature of the relationship.[51] As mentioned, a factor considered in the determination of status may be payroll practices. The deduction at source for income taxes and employment insurance would tend to suggest an employment relationship.[52] The actual existence of such facts would, again, be merely persuasive and not conclusive.

The aforementioned tests of employment status can, therefore, be applied to the undergraduate and graduate student relationships with universities. With respect to undergraduate students, these individuals are often employed as either research assistants or teaching assistants. The positions are generally part-time and provide hourly compensation for the performance of specified tasks.

In the undergraduate-student fact situation, the student is likely hired to perform tasks that are not, in and of themselves, going to create any intellectual property. Photocopying case law for a law professor or replicating

experiments for a genetics researcher are both situations where the student would not create intellectual property. A research student or teaching assistant at the undergraduate level is rarely skilled enough to generate intellectual property, and it is generally not expected from them (and consequently not in their job description). Based on the indicia of employment law, the undergraduate student provides services at either an hourly or salaried rate based on the directions of a supervisor. The student does not possess the risk of loss nor the chance for profit. Therefore, the classic indicia would tend to suggest that undergraduate research assistants would be employees.

However, the scope of that employment would not reasonably include generation of patentable innovations, although it may include the generation of copyrightable materials. Therefore, if it is outside the job description to patent and innovate, then any patents or innovations that are created would be property of the student, regardless of whether the student used the university facilities or not.[53]

The following passage provides an excellent summary of this issue: "Suppose a factory manager uses the workplace to improve the operation of a machine her employer owns. If not hired or paid to invent, the employee owns and can patent for herself any innovation resulting from her experiments. *The employer has no legal or moral claim to the fruits of employees' intellectual labor simply because it provided a propitious environment for invention or encouraged its employees' endeavors.*"[54] [emphasis added]

The second situation common for undergraduate students is the creation of intellectual property in their course work. Clearly, where a student is paying to attend a university, it would not be an employment relationship where tasks are being performed to complete the requirements of course work or other degree requirements.

Graduate students are generally not going to be considered employees of a university. The key factor that is often misleading with graduate students is the fact that they do generally receive a stipend as income for their attendance at a given university. However, the key distinction that should be noted is that a person other than the university (at which point the university does not generally provide any additional funds) may provide the stipend. In the scientific research communities, stipends may be provided by the private sector or from charitable organizations that wish to support particular fields of research. Should the university not actually pay the graduate student, then it is clearly not an employment relationship of any type, as the student is paying tuition to complete his or her course requirements, not being paid for his or her contribution.[55]

The second point that makes an employment-based argument unfeasible with regards to graduate students is the completion of degree requirements. As the graduate student is working toward his or her thesis (generally), he or she will perform many tasks that are not assigned. In fact, the satisfaction of degree requirements clearly does not stipulate the manner in which the work is to be performed and, specifically, does not require the development of any intellectual property except for the thesis that is protected only by copyright. Of course, to even consider degree requirements as a job description would require a finding that the stipend would be an employment-based remuneration. Given the generally long hours worked by students and the relatively small stipend that they receive, the hourly rate of pay would fall well below minimum wage. If it were a true employment relationship, the remuneration by stipend would have to be significantly higher to reflect the proper amount of work performed.[56]

Presently, the stipend paid to graduate students by their university is classified, rightly, as an academic award and, for taxation purposes, it is treated as such.[57] It should be noted, however, that there are occasions when a graduate student may work on a research project simply for the sake of earning revenue to pay the bills, and, as such, an employment relationship may exist. In this instance, the type of employment and terms should be made clear upon hiring.

In conclusion, it appears that the employment camp (and the employment model in general) is inadequate to properly explain the way in which universities could justify ownership of student-created intellectual property or the granting of secondary rights in student-owned intellectual property. It would appear, except for the students who are working as paid assistants and who create copyright-protected material, that the university cannot effectively rely on an employment model to effectively justify a claim that it is the proper owner of student-created intellectual property. To effectively gain ownership of student-created intellectual property, a further contractual document would have to be executed that would be mutually agreed upon by the student and the university. The other position that may explain this apparent incongruity is the contract camp.

The Contract Camp

The foundation of a university's claim on student-created intellectual property may be better justified by a discussion of the contract camp. The contract camp can best be described as the belief that the students, at one point or another, will sign a document or otherwise indicate agreement with the university policies as a precondition of their attendance of that institution. This document does not tend to discuss intellectual property matters. Either the policies are referred to directly; or more likely, the student is agreeing to abide by the rules of some variety of student handbook.

This student handbook would then, in turn, include a reference to the student being bound by the university policies. The contract-camp position states that the incorporation of university policies into these documents would bind the student to the terms of the university policies (including terms regarding intellectual property ownership or secondary rights). The contract camp is by far the stronger of the two camps regarding why the university should own student-created intellectual property.

There are complications, however, with the contract camp. The foremost among these problems are very basic principles of contract law. Assuming that the formalities of offer and acceptance are met[58] and that there is a properly executed document of the terms mentioned above, branches of the doctrine of unconscionability provide the primary grounds to set aside the alleged contractual obligations of the student. The courts have a long and eventful history of construing contracts in a way that secures a just result where one of the parties is in a substantially weaker bargaining position. Historically, there have been many cases that have led to the creation of certain common-law principles that attempt to remove the burden of an improvident bargain made by a less-sophisticated party.

One of the potential problems with the contract camp is the argument of *non est factum*. *Non est factum* stands for a variety of principles, but one of its concepts is that the signature on a signed document is invalid because of a mistake as to the nature of the document. In the present situation, it is unlikely that any university student knows that he or she is effecting an assignment of intellectual property when, in fact, he or she is the person paying for and receiving the service (education). The nature of the document is, in effect, a document that serves as acknowledgement of the student's payment and registration (presumably) and not one that indicates that the student is paying thousands of dollars per year to grant his or her intellectual property to the university.

In a way, the *non est factum* issue is one of unconscionability in that it deals with the incorporation of documents that are not known to the student at the time of acceptance; however, it does not deal with unconscionability directly. In the present situation, it is stated succinctly that the university policies (not withstanding the incorporation by reference issues) do not contain the magic words of conveyance. There is often no term stating that the student conveys his or her future intellectual property interests to the university. The university simply assumes that it is the owner. Without express language of conveyance, it would appear to the student (or anyone) that the document is not one of conveyance but rather a document stating a fact (albeit a potentially incorrect one). The best way to resolve this issue is to discuss unconscionability issues, specifically the incorporation of documents and the nature of unsigned documents that purport to govern contractual relations. The *non est factum* argument can be used to bolster any independent findings of unconscionability.

Unconscionability with respect to unsigned documents and those documents that are incorporated by reference is one of the more daunting problems facing the contract camp in this analysis. Generally, contract law holds that a document handed over by one party to the other at the time of the contract may be incorporated into the agreement if the document is the sort of document generally known to contain contractual terms and if the party seeking to rely on the document has taken reasonable steps to bring those terms to the other's attention.[59]

The Ontario Court of Appeals has stated that: "In my opinion, the [jury] … question should have been followed by another question to establish whether Strand had taken reasonable measures to draw the limitations and conditions of the contract to the customers' attention. If they did, the respondents ought to have been familiar with them and could not successfully rely on their unreasonable failure to read them."[60]

Some English and Canadian courts have taken a much stronger position on this point. Pronouncements on this point are quite strong, as can be seen from the following statements made by Lord Denning's famous comment: "Some clauses, which I have seen, would need to be printed in red ink on

the face of the document with a red hand pointing to it before the notice could be held to be sufficient."[61]

Denning also identified equality of bargaining power as an important factor to consider when discussing the incorporation of documents. He stated: "That was the case of a private individual … The plaintiff there was not of equal bargaining power … The conditions were not incorporated. But here the parties were both in the trade and were of equal bargaining power."[62]

These doctrines relating to the incorporation of unsigned documents and the enforceability thereof has been considered, helpfully, in reference to university calendars.[63] The case of *Governors of Arcadia University v. Sutcliffe* considered whether a university calendar containing a rule stating that a student withdrawing early from a residence during a school year would still be required to pay the full-year residence fees was, in fact, a contractual document.[64] It held that the calendar was, in fact, a contract and that the student was bound to those terms because the student agreed, because of his registration at the school, to be bound by the calendar terms.[65]

Sutcliffe merits more extensive discussion in light of the remarkably settled common law in this field to make sense of what it would mean in the context of the conveyance of intellectual property. The first point that one can see is that a residence and the terms of living in a residence were brought to the students' attention through the use of a calendar (and, in this particular circumstance, after the fact, through the residence handbook). Also, it is reasonable to believe that there would be terms and conditions in the calendar that would regulate rental of housing. If it were housing provided outside the university community, there would be no doubt that a lease or a rental agreement could be required. It would seem that the case is properly decided based on the settled common law because the nature of the terms, although onerous, were of the kind that the student ought reasonably have expected to encounter when obtaining a residence room.

The court in *Sutcliffe* relied upon the case of *Polten* on this point; however, *Polten* does not give extensive treatment of the subject matter and rather relies in its entirety on an English case.[66] This English case, *University of Ceylon v. Fernando*, is one that is concerned primarily with the procedural fairness of the appeal process in place at a particular university. It does not discuss the enforceability of the provisions nor unconscionability. In *Fernando*, those issues were not raised.

Specifically, the passage on which *Sutcliffe* and *Polten* blindly rely is completely insubstantial. *Fernando* performs no detailed analysis nor does it cite any justification to support the broad contention that a student is bound to the terms.[67] Rather, it states that a student cannot insist on a procedural remedy in a hearing above that which is provided by statute. In effect, the court is stating that statutory procedures are deemed accepted, not necessarily those policies adopted by a nonpublic university board of governors. The *Fernando* case might very well be decided differently given present-day jurisprudence given the lack of foundation authorities.

If *Sutcliffe*, *Polten*, and *Fernando* are considered correctly decided, however, they all share two very notable flaws that may make them generally inapplicable to the present situation of university intellectual property policies. The first flaw is the fact that the students may not have notice (through a calendar) of the terms of the intellectual property policy; rather, they would have to seek out the relevant university senate policy to read the text (the opposite was true in *Sutcliffe*, *Polten*, and, to a lesser degree, *Fernando*).

Second, the assignment of intellectual property may not be something that is within the reasonable contemplation of a student when he or she is deciding to attend an institution (again, the policies in *Sutcliffe*, *Polten*, and *Fernando* were policies that traditionally would be contemplated). Given such an alteration of the facts and the present jurisprudence on incorporation of unsigned documents, it would appear that the *Sutcliffe*, *Polten*, and *Fernando* decisions are not of any immediate assistance, although they do assist significantly in classifying the relationship of university and student as, generally, one of contract. It would be overstating their effect to cite them as authority holding all university policies as enforceable, regardless of their terms.

As mentioned by Lord Denning and quoted above, the inequality of bargaining power may be an important factor to examine when determining the enforceability of a document that is incorporated by reference. It may also serve as a ground to set aside the agreement in and of itself. The English and Canadian authorities support the notion that weaker parties may be protected from an improvident bargain on the grounds of inequality of bargaining power, specifically as a branch of the unconscionability doctrine.[68]

Many cases have adopted the concept of inequality of bargaining power; however, the modern Canadian position on this principle is that

there will be a finding of an unconscionable bargain made by a weaker party to grant relief from "an immoderate gain or undue advantage taken of inequality of bargaining power."[69] Specifically, age[70] and lack of business experience[71] have been held in Canada as proper situations justifying relief. It would be fair to say that most late teens entering into university for the first time and, for the most part, most graduate students (generally in their mid-twenties), are both young and inexperienced with respect to business, and they might very well make quite improvident bargains and never know the consequences of their actions. Signing a document that purports to incorporate an unlimited assignment of intellectual property as a precondition of attending a university may be classified as such an improvident bargain, although it is a point that would likely have to be decided by a judge.

Another ground on which the validity of the university policies is suspect is that of duress. The duress at issue here is not one of anticipated physical harm but rather one of economic threat. The students are asked to sign forms as a condition of their acceptance after already forgoing other postsecondary-school opportunities. Once a student reaches the point where he or she is asked to sign a student card or university document with his or her registration, he or she has likely already indicated that he or she would not attend another institution. Assuming that the student is given notice of the university policies, the student would have no choice but to sign up or wait until the next admissions cycle to apply to a different school.

At which point, the cost/threat to the student of not signing the document would be one year of earning potential at the end of his or her career (when he or she is paid the most). Depending on the student's academic (earning) potential, that future income he or she might have to forgo has immense value, even in present-day dollars. It is an extreme business pressure under which the student must decide. Business pressures have in many cases been tolerated by the courts;[72] although, recent cases have openly recognized economic duress as a defense. It has been held that economic coercion can amount to duress. The Privy Council and the House of Lords also approved these cases.[73] The substance of these cases has been imported into Ontario and, arguably, all of Canada.[74] In essence, however, this hurdle to overcome would be best dealt with through an unconscionability discussion.[75]

There are several cases that do not fit into any particular contractual framework. These cases, however, specifically discuss the contractual relationship between a university and student. In the case of *Attaran v. University of British Columbia*,[76] it was a situation where students of the University of British Columbia challenged a fee increase. That case was of procedural fairness in an administrative-law context. Therefore, it is not immediately applicable to the present analysis. Further, if it were applicable, it could not be utilized by the university to claim intellectual property under its administrative authority, as *Attaran* tends to lend support for a person challenging the use of administrative authority.

In the case of *Balanyk v. University of Toronto*,[77] a postgraduate fellow at the University of Toronto claimed that duress was used in extracting an assignment of intellectual property in an invention that was co-invented by the plaintiff Balanyk. In *Balanyk*, the court held that the subsequent assignment was without duress and that the rights of Balanyk were not violated by subsequent licenses that were issued by the University of Toronto's licensing venture. This case does not lend clarity to the present analysis because it does not discuss a university policy that claims to extract intellectual property ownership; rather, it deals with an independent assignment that was entered into separately from the student-university relationship.

Finally, there is the case of *Wong v. Lakehead University*[78] that deals with representations made in the student calendar to a potential graduate student. *Wong* clearly states that the calendar constitutes "an invitation to treat and not a promise or an offer."[79] That would not tend to lend support to a university's attempt to rely on a calendar to transfer intellectual property. However, the student was successful in relying on a subsequent document provided by the university and the student's subsequent enrollment as a collateral contract.[80] A university would have trouble relying on *Wong* unless a university calendar set out the intellectual property and then later referenced that property in a subsequent offer of admission that required execution by the potential student.

It would appear, after considering the various issues relating to the contract camp, that the matter is not nearly as clear or resolved as the employment camp. There are valid positions that may be taken on either side of a contract-law-based argument. The resolution of these issues is likely to consider equity principles of fairness and reasonableness. To predict a likely outcome with certainty would be suspect given the highly fact-specific nature of these cases.

It can be seen from the authorities, however, that universities have a difficult case to overcome should a student challenge a regime whereby the university purports to own the student's intellectual property or retain any secondary rights therein. The student position in such litigation would rest on strong and well-settled principles of common law, and the university would bear the burden of proving that the present situation is justifiable.

Conclusion and Recommendations

This paper set out to examine inherent presumptions of ownership rights within Canadian university policies. The first conclusion that can be made is that several universities presume that they have ownership of the intellectual property produced by their students; however, not all universities make these assumptions. The state of the law does not correspond with such a presumption, and, presumably, those schools that are operating under such a presumption are doing so with some degree of risk. Although a university may claim that the students are employees to a certain degree, a university cannot rely on the employment camp to justify the vast majority of the interests they purport to own in student-generated intellectual property.

Should the university claim that there is a contractual nexus between the student and the university that conveys the intellectual property, and if the terms are clear and explicit, the university would have to defend against strong allegations of *non est factum* and unconscionability. Serious policy concerns exist in favor of and against permitting the university to retain ownership of student-created intellectual property. These policy concerns are not determinative, although they provide an important context for deciding any litigation on this matter. It cannot be said exactly whether or not a university policy is sufficient to convey intellectual property rights. What can be stated is that there are significant issues a university must deal with should a student decide to challenge a university policy.

The recommendations that flow from the conclusions are straightforward. The real problem faced by universities is ensuring, if they wish to engage in commercialization of intellectual properties, that they have secured the proper rights from the creators. The old axiom regarding an ounce of prevention certainly applies in this context. If a university desires to rely on its intellectual property policy, the first recommendation is that the university should take some simple, cost-effective, steps. These steps include the following:

- *Alter the university policies to include conveyance language.* As the policy is the document on which one may ultimately have to rely, it should be clear and unambiguous that there is an agreement to convey future rights in intellectual property. This would include the use of wording such as, "Student agrees to convey to university…"
- *Establish and maintain a joint student-faculty panel that discusses intellectual property issues and reviews the policies on a regular basis.* Universities presently utilize joint student-faculty panels for tasks such as reviewing animal-based experiments for approval and for the selection of employees or faculty. These types of panels would be effective in ensuring that the students who are subject to these policies actually craft the policies themselves (in conjunction with the responsible faculty). A tangential benefit is that students may not as readily challenge a policy where it was drafted with student input; whereas, the students may be eager to challenge a policy written without their input.
- *Inform prospective students early in the admissions process of intellectual property concerns.* The university produces materials and conducts seminars promoting their institution to prospective students. These materials and seminars should make students aware that intellectual property concerns exist and be clear as to the university's policy. This brings the issue to the attention of the students and assists the university in arguing that intellectual property concerns were in the reasonable contemplation of the students when they apply.
- *Enclose a separate agreement with any offer-of-admission packages.* Universities should include a separate form with a copy of the university policy attached indicating that compliance with this policy is a condition of attendance and requesting a signed response prior to accepting a position at the school. This preempts several issues. Ideally, this form would contain a representation that the student has obtained legal advice, although that is likely not required if the form is drafted in plain language. Also, the student will have the ability to decline the offer and accept other positions. The economic undue-influence argument would be greatly reduced in that case. This separate agreement should not be presented at the time of registration where the student is most likely not to consider such matters and be subject to duress.
- *Have all researchers sign and direct their staff to sign an assignment of*

intellectual property rights prior to commencing work on new projects. Project-by-project assignments may be more difficult to manage for the university, but would allow the university to ensure that intellectual property interests are assigned where required because of cooperation with the private sector. This is similar to what corporations do annually. Often, corporations will circulate a compliance-with-corporate-policies agreement wherein the employee agrees to all the policies and is told to read them prior to signing. This practice may be in place now for many schools, but it should be stressed that the only way such an approach is effective is where the entire community participates.

- *When in doubt, be fair to the students and execute new agreements.* Given the uncertainty of the enforceability of these policies, the university should be cautious and execute a new negotiated agreement that supercedes all prior arrangements when there is a dispute as to whether or not a student owns certain intellectual properties. In the long run, it may be advantageous to compromise occasionally rather than risk having university ownership policies vigorously challenged in court. If the university lost once in court, it could open up the opportunity for future claims by past students. There is, consequently, an intrinsic benefit in keeping these matters away from the courts.

In summary, there are significant legal issues that are not being presently addressed by many, if not most, Canadian universities. Without careful processes and diligent management, Canadian universities currently have questionable rights to the intellectual property created by their students. With some foresight, the universities can effectively protect themselves and their policies with the use of several well-designed processes including those mentioned above.

Whether or not a university should attempt to gain interests in the intellectual property created by students remains a philosophical one. A university must decide the degree to which it is a business and the degree to which it is an educational institution. Specifically, whether its proper role is to earn revenues or educate students. What is relatively clear is that universities that claim some ownership interest or entitlement to royalties may not be dealing fairly with their students, as it may be perceived that those universities are attempting to earn revenues and gain distinction not based on their own initiatives but, rather, the unsolicited initiatives of their students.

Notes

[1] See: Personal Web site, www.warble.com/jherbert/giants.html (date accessed: April 6, 2000).

[2] *Ibid.*

[3] It should be noted that, although there is no direct evidence that these policies have been created in direct response to the growth in the importance of intellectual property rights, there is indirect evidence of such a response. Many universities have recently created technology transfer corporations (see, for example, University of Toronto, University of Waterloo, *inter alia*). The recent growth of technology transfer entities would tend to suggest (albeit indirectly) that universities are, in fact, responding to the growth of intellectual property. Further, there have been policy developments in the United States and Canada that would tend to suggest that unless the universities themselves take steps to manage and implement intellectual property policies such as the *Bayh-Dole University and Small Business Patent Procedures Act* Pub. L. 96-517, § 6(a), Dec. 12, 1980, 94 Stat. 3019 [hereinafter "*Bayh-Dole Act*"]. *Bayh-Dole Act* is contained in 35 U.S.C.A. §§ 200 to 211. The Canadian Advisory Council on Science and Technology via the Expert Panel on the Commercialization of University Research prepared a report entitled "Public Investments in University Research: Reaping the Benefits," dated May 4, 1999, [hereinafter the "GC Report'] that provides valuable context for any discussion of intellectual property created within Canadian universities. The *Bayh-Dole Act* and the *GC Report* will both be raised again with respect to the recommendations and conclusions of this article.

[4] Nika Ketis, John Rudolph, and Micheline Gravelle, "Ownership of Intellectual Property in Canadian Universities," Bereskin & Parr Web site, www.bereskinparr.com (date accessed: April 6, 2000) and *AUTM Newsletter*, December 1998.

[5] This is not an exhaustive list. Also note that these are very broad characterizations and that a specific reading of each university's calendar and policy should be performed prior to relying on this chart as a definitive guide. Each fact situation is different, and many of these are policies that are quite nuanced. In some situations, a university may

assert ownership rights where the chart indicates that they do not. The chart attempts to provide a representation of the general policy and not the specific elements of each policy. For a discussion of the specific elements of each policy, one should consult, Ketis, *supra* note 5 at Table 2. Note also: chart current as of the time of the aforementioned publication, amended policies are not reflected (and, incidentally, are not overly relevant to this article's discussion of the broader policy issues). It should be noted that although the ownership rests with the inventor or creator in these situations, there are often terms that would purport to require a compulsory license or assignment on dictated terms back to the university. An example of this is the University of Toronto intellectual property policy that requires the assignment of either *(a)* a 75 percent interest in all patents to the university in exchange for the university managing commercialization or *(b)* a 25 percent interest in all patents to the university and the inventors must commercialize the product themselves. These purport to be terms not unlike those that convey ownership. Similar issues to those encountered by this article's analysis of ownership are raised that can be analyzed in the same analytical framework as will be proposed. It is possible that the forced assignments or licenses would be unenforceable.

In addition, the analysis performed by Ketis was not limited to students and also includes some policies that apply to employees or faculty members. Note that the classification applied here is important only to indicate that there is a clear consensus trend to claim some sort of royalties from research performed by university students. The classification is based on mandatory and nonmandatory nature of the regimes not the precise language. For the sake of brevity, this chart refers only to patent revenues and not copyright or other intellectual property revenues.

[6] Ketis, *supra* note 4 and Statistics Canada (Science and Technology Redesign Project), "Survey of Intellectual Property Commercialization in the Higher Education Sector, 1998" Document 88F0006XPB No. 1 (available via Internet at: www.statcan.ca/english/IPS/Data/88F0006XIB97011.htm) [hereinafter the *Statistics Canada Report*]. Please note that all averages in the summary table above are simple averages and are not weighted averages derived from the *Statistics Canada Report*.

[7] It bears noting that, with respect to the Ketis study, the 6 percent where there is no ownership interests or secondary rights claimed by the university represents only one university, namely the University of Western Ontario.

[8] These maintenance obligations may include country-specific patent registration, patent prosecution, litigation of infringement, *inter alia*. Further, it should be noted that this concept is fundamentally contrary to the *GC Report*, *supra* note 3 at p.3, which states that: "The Panel also believes that the benefits arising from these commercialization opportunities must be shared with the creator(s) of the IP. University researchers do not need to own IP in order to benefit from successful commercialization undertakings." It is submitted that the *GC Report* has mistakenly understated the intrinsic value of intellectual property ownership.

[9] David Vaver, *The law of intellectual property: copyright, patents, trademarks* (Concord: Irwin Law, 1997) at p.21; Copyright Act, R.S.C. 1985, c.C-42 as amended (current to S.C. 1999, c.2 ss.45,46) at s.13(1) [hereinafter "CA"]

[10] *Ibid.* (excluding reference to CA).

[11] *CA*, *supra* note 9 at s.13(4).

[12] *CA*, *supra* note 9 at s.13(3).

[13] *Ibid.*

[14] *Ibid.*

[15] Gregory C. Ludlow and Anne M. Godbout, "Survey of Intellectual Property Part IV – Patents" (1998-1999) 30 Ottawa L. Rev. 117 at para. 178.

[16] Vaver, *supra* note 8 at p.146. See also: *Christiani & Nielson v. Rice*, [1930] S.C.R. 443, affirmed [1931] A.C. 770 (P.C.).

[17] Ludlow and Godbout, *supra* note 15 at para. 178.

[18] Vaver, *supra* note 9 at p.147.

[19] *Ibid.* at p.148, *Comstock*, *infra* note 22 at p.51–57

[20] *Ibid.*

[21] It should be noted that the United States Patent Office may have different rules with respect to registration of patents (specifically with respect to patents created by employees through the scope of their employment).

[22] *Comstock Canada v. Electec Ltd.* (1991), 38 C.P.R. (3d) 29, 45 F.T.R. 241 (F.C.T.D.) (cited to CPR, hereafter) [hereinafter "Comstock"].

[23] *Comstock*, *supra* note 22 at p.54.

[24] *Ibid.* at p.55.

[25] *Ibid.* at p.50.

[26] *Ibid.* at p.50.

[27] *Techform Products Ltd. v. Wolda* [2000] O.J. No. 4505 (Ont. C.A.) [1999] O.J. No. 3820 (Ont. C.A.) [1999] O.J. No. 3069 (Ont. Sup. Ct. Jus.) [1998] O.J. No. 3364 (Ont. G.D.); reference specifically made in the Ont. Sup. Ct. Jus. decision at paragraph 7.

[28] *Seanix Technology Inc. v. Ircha* (1998) 78 C.P.R. (3rd) 443 [hereinafter "*Seanix*"]

[29] *C.I. Covington Fund Inc. v. White et al.* (2000) 10 C.P.R. (4th) 49 [hereinafter "*Covington*"].

[30] Vaver, *supra* note 9 at p.237.

[31] A discussion of compulsory licenses is beyond the scope of this paper. These licenses may require an intellectual property rights holder to provide a license at a statutory royalty rate or some other reasonable rate to prevent anticompetitive conduct by rights holders.

[32] Notwithstanding that copyright law does not share with patent law the concept of a mandatory license.

[33] It should also be noted that these two points of view are not exclusive of the other. They are presented separately for the sake of clarity and simplicity, but both of these viewpoints may interact.

[34] See notes 37, 38, 39.

[35] See note 44.

[36] *Ibid.*

[37] *Short v. J & W. Henderson Ltd.* [1946] S.C. 24 (H.L.), applied in Canada in *Baldwin v. Erin District High School Bd. et al.* (1962), 36 D.L.R. (2d) 244 (S.C.C.0, affirming [1961] O.R. 687, reversing [1961] O.R. 146.

[38] *Ibid.*

[39] See: *Re Parkin Elevator Co.* (1916), 37 O.L.R. 277 (Ont. C.A.); *Humphreys v. City of London*, [1935] O.R. 295 (Ont. C.A.).

[40] [1947] 1 D.L.R. 161 (P.C.), affirming [1945] S.C.R. 621, reversing in part a prior decision of the Quebec Court of Appeal. [hereinafter "*Montreal*"].

[41] *Ibid.*

[42] *Ibid.*

[43] As indicated, for example, in: *Preston Developments Inc. v. Canadian Surety Co.* (1993), 1 C.C.E.L. (2d) 1 (Sask C.A.).

[44] *Re Telegram Publishing Co. Ltd.* [1982] 4 W.W.R. 619 (B.C. Co. Ct.).

[45] *Mayer v. J Conrad Lavigne Ltd.* (1979), 27 O.R. (2nd) 129 (Ont. C.A.); *Marks v. Cresson Investments* (1986) T.L.W. 619-019 (Ont. H.C.); *Elliot v. Cardinal Insulation Inc.* (1987), T.L.W. 719-021 (Ont. H.C.); *Roberts v. Libman & Co.* (1991), 38 C.C.E.L. 240 (Ont. Gen. Div.).

[46] *Roberts*, *supra* note 45.

[47] *Walden v. Danger Bay Productions Ltd.* (1994), 3 C.C.E.L. (2nd) 78 (B.C.C.A.).

[48] See: *Re Telegram Publishing Co Ltd. et al.*, *supra* note 44.

[49] *Walton v. Volpi* (1994), 6 C.C.E.L. (2nd) 125 (Ont. Gen. Div.).

[50] *Ibid.*

[51] See: *Queensbury Enterprises Ltd. v. J.R. Corporate Planning Associates*

Inc. (1987), 19 C.C.E.L. (Ont. H.C.), affirmed at 27 C.C.E.L. (Ont. C.A.); *Jaremko v. A.E. LePage Real Estate Services Ltd.* (1987), 59 O.R. (2nd) 757 (Ont. H.C.), affirmed at 69 O.R. (2d) 323 (Ont. C.A.).

[52] *Thomson v. Commercial Print-Craft Ltd.* (1984) T.L.W. 319-025 (Ont. H.C.).

[53] Vaver, *supra* note 9 at p. 148.

[54] *Ibid.*

[55] It should be noted that, where funding is provided by entities other than the university, the funding is usually funneled through the university in order to ensure that students (especially foreign visa students) are paid only by the university.

[56] It should also be noted that the graduate student stipend generally does not include time spent as a teaching assistant. Graduate students, when employed as teaching assistants, are generally compensated separately from their stipend. Thus, it could be further argued that the employment relationship is a separate and distinct relationship from the actual fulfillment of degree requirements.

[57] Interpretation Bulletin IT-75R3 – *Scholarships, Fellowships, Bursaries, Prizes, and Research Grants*, paras. 5-9, 10-12, 20-23. The interpretation bulletin collectively states that if research, scholarship, or discovery is the primary purpose of the fellowship or grant that it should be classified as a scholarship and not as income from employment.

[58] These formalities are not at the root of the contract-camp analysis. However, in the interests of clarity, the offer-acceptance pair could be fulfilled in many ways. The offer may be the offer of a position at a school, followed by the student's indication that they wish to attend the institution. Perhaps a better example is to view the former offer-acceptance as an invitation to treat and to consider a student's attempt to register at the university as an offer to attend on the terms specified on the university's registration form. The university's registration of the student for classes would constitute the acceptance element. Regardless of the way in which offer-acceptance is classified, there are certainly more than two plausible ways in which to establish this element, and a court would certainly not consider the relationship contractual to some degree. See also note 56.

[59] S.M. Waddams, *The Law of Contracts*, 3rd ed. (Aurora: Canada Law Book Inc, 1993) at para. 62. Also: Waddams cites the following cases in support of this position: *Parker v. South Eastern Rwy. Co.* (1877), 2 C.P.D. 416; *Grant Trunk Ry. Of Canada v. Robinson*, [1915] A.C. 740. 22 D.L.R. 1 (P.C.) and Bata v. City Parking Canada Ltd. (1973), 43 D.L.R. (3d) 190 (Ont. C.A.).

[60] *Craven v. Strand Holidays (Canada) Ltd.* (1982), 142 D.L.R. (3d) 31 (Ont. C.A.), leave to appeal to the S.C.C. was denied at 48 N.R. 320.

[61] *J. Spurling Ltd. v. Bradshaw*, [1956] 1 W.L.R. 461 (C.A).

[62] *British Crane Hire Corp. Ltd. v. Ipswitch Plant Hire Ltd.* [1975] Q.B. 303 (C.A.) It should be noted that on the point of equal bargaining power, the Court of Appeals reversed Denning's finding in order to reverse the result but leave the principle of law intact.

[63] *Governors of Acadia University v. Sutcliffe* (1978), 85 D.L.R. (3d) 115 (N.S. Co. Ct.), affirmed at 95 D.L.R. (3d) 95 (S.C. App. Div.) [hereinafter "*Sutcliffe*"].

[64] *Ibid.*

[65] *Ibid.* at p.101. See specifically: *Re Polten and Governing Council of University of Toronto et al.* (1975), 59 D.L.R. (3d) 197 at p.202, 8 O.R. (2d) 749 at p.754 (Ont. Div. Ct.) [hereinafter "*Polten*"].

[66] *University of Ceylon v. Fernando*, [1960] 1 All E.R. 631 at p.639 [hereinafter "*Fernando*"].

[67] *Ibid.*

[68] Waddams, *supra* note 59 at para 511.

[69] *Ibid.* citing: Crawford, "Comment," 44 Can. Bar. Rev. 142 (1966).

[70] Waddams, *supra* note 59 at para. 511 and see: *Knupp v. Bell* (1966), 58 D.L.R. (2d) 466 (Sask Q.B.), aff'd 67 D.L.R. (2d) 256 (C.A.);

Marshall v. Canadian Permanent Trust Co. (1968), 69 D.L.R. (2d) 260 (Alta. S.C.) *inter alia*.

[71] Waddams, *supra* note 59 at para. 511 and see *inter alia: Paris v. Machnick*, (1972), 32 D.L.R. (3d) 723 (N.S.S.C.T.D.); *Easton v. Sinclair*, (1912), 3 D.L.R. 652 (Ont. H.C.J); *Taylor v. Armstrong*, (1979) 99 D.L.R. (3d) 547 (Ont. H.C.J.); *Buchanan v. Canadian Imperial Bank of Commerce*, (1979), 100 D.L.R. (3d) 624 (B.C.S.C.) var'd 125 D.L.R. (3d) 394 (C.A.).

[72] See: *Peter Kiewit Sons Co. v. Eakins Construction Ltd.* (1960), 22 D.L.R. (2d) 465, [1960] S.C.R. 361. See Waddams, *supra* note 59 at para. 503, note 249 which lists *inter alia* the following cases: *Morton Const. Co. Ltd. v. Corporation of City of Hamilton*, (1961), 31 D.L.R. (2d)323 (Ont. C.A.); *United States v. Bethlehem Steel Corp.*, 315 U.S. 289 (1942); *Royal Bank of Canada v. Siemens* (1978), 82 D.L.R. (3d) 527 (B.C. Co. Ct.); and *Thermo-Flo Corp Ltd. v. Kuryluk* (1978), 84 D.L.R. (3d) 529 (N.S.S.C.T.D.).

[73] *Pao On v. Lau Yiu Long* [1980] A.C. 614; *Universe Tankships of Monrovia v. Int. Transport Workers Federation*, [1983] 1 A.C. 366 (H.L.); *Dimskal Shipping Co. S.A. v. Int; Transport Workers Federation*, [1991] 3 W.L.R. 875.

[74] See: *Gordon v. Roebuck* (1992), 92 D.L.R. (4th) 670, 9 O.R. (3d) 1 (C.A.) which applies *Pao On*, *supra* note 73 (one above).

[75] As suggested by Waddams, *supra* note 59 at para. 507.

[76] *Attaran v. University of British Columbia* [1998] B.C.J. No. 115 [hereinafter "*Attaran*"].

[77] *Balanyk v. University of Toronto* (1999) 1. C.P.R. (4th) 300 [hereinafter "*Balanyk*"].

[78] *Wong v. Lakehead University* [1991] O.J. No 1901 [hereinafter "*Wong*"].

[79] *Ibid*.

[80] *Ibid*.

Gap Funding in the United States and Canada

Steven C. Price and Philip Z. Sobocinski

Introduction

The flow of technology from universities to the private sector is often pictured as following a linear path. Such models start at one end with basic research and continue consecutively with applied research, development, design, scale up, trial production, tooling up, manufacturing, and, finally, sales at the other. Universities are generally modeled as being in the basic and applied areas, though they also engage in some developmental work.

However, it is the development stage that constitutes the bottleneck where much technology transfer at universities comes to a halt. It is not unusual for university research to evolve to a point where obtaining traditional federal funding is difficult because the work is too applied. Obtaining industrial support is often improbable, because the work is considered too basic. And, when research is needed for the sole purpose of broadening patent claims or enhancing licensing possibilities, acquiring funding is difficult and often unlikely.

The result is a developmental no man's land where promising technologies arising from university research can languish for lack of even a modest amount of research support. The phrase *gap funding* is often used to describe institutional programs that provide funds that fill this need or gap.

This paper will report on two programs at the authors' institution, offering them as case studies that demonstrate the importance of gap funding. In addition, results of a survey conducted on the status of gap funding for technology programs in North America are presented. Outcomes are shared, the financial and administrative structure of both University of Wisconsin–Madison programs—the Industrial and Economic Development

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Research Program and the Robert F. Draper Technology Innovation Fund—are described, and helpful tips are presented.

The paper concludes that programs that provide for gap funding are critical and add significant value to technology development within a university setting.

Closing the Gap

Several universities have established funding programs to alleviate this gap in funding. However, such programs are heterogeneous in that they differ greatly in purpose and management from one university to another, ranging from something in the nature of a slush fund at some institutions to venture-capital-type programs at others.

In an attempt to determine the importance and status of gap-funding programs in the United States and Canada, the authors conducted an informal survey. The survey was administered by e-mail; the content of which is shared below. It was forwarded to technology transfer officers representing approximately thirty institutions. Some officers shared the survey with additional colleagues; thus, the total number of recipients surveyed is more than thirty.

Survey

This is the script used for the survey: "I'm doing a survey of university technology transfer offices that have money available for gap funding. By gap funding I mean money directed to prototype development, feasibility demonstration, reduction to practice, and/or fleshing out claims. I have four questions: (1) Does your institution have such a program? (2) How long has the program existed? (3) Has an analysis been done of outputs (leveraged money, patents, students trained, etc.)? (4) What is the budget per year for this funding?"

The results to these questions as provided by the participants are presented in table 1. It is apparent from a review of the results that very few analyses regarding outcomes of these types of programs have been completed.

The authors' institution, however, has two such programs for gap funding, both of which have been in existence for many years and are listed in table 1. Each has a somewhat different focus, and each shows positive outputs. Results derived from these programs are presented as two sample case studies.

Table 1

Gap-Funding Programs Affiliated with U.S. and Canadian Universities Based on a Survey of at Least 30 Major Research Universities through 1999

Affiliated University	Name of Fund	Approximate Size of Funding Program	Outputs Analyzed?	Year Established
Argonne National Laboratory/University of Chicago	ARCH	Initially established with $9 million, ~$500,000/y	Yes, not available	
Beth Israel Deaconess Medical Center		$100,000/yr	Yes, not available	
Boston University		$5,000–$50,000/yr	No	
California Institute of Technology		$400,000/yr	Yes, five companies started	
Georgia Institute of Technology	Advanced Technology Development Program	$400,000/yr	Yes, not available	1992
Iowa State University		$200,000/yr	Yes, not available	1996
Kansas State University and other state schools	KAW Holdings LLC	Established with $800,000/yr	No	
Kansas State University	Manhattan Holdings LLC	Established with $1.8 million	No	1997
Purdue University	Trask Fund	$200,000–$400,000/yr	No	1974
Queen's University	1. Venture fund	Established with $7 million	No	1999
	2. Development fund	$100,000/yr	No	1994
Simon Fraser University		$100,000/yr	No	
Stanford University	Birdseed Program	$210,000 spent since inception	No	1997
Texas A&M University	AM Fund	Established with $14.5 million	No	
University of British Columbia	Prototype Development Fund	$300,000/yr (1989–1995)	Yes	1989
University of Kansas	Precede Fund LLC	Established with $750,000	No	1999
University of Michigan		1. $50,000 from office of vice president	No	1994
		2. $300,000 from medical school		1997
		3. $100,000 from College of Engineering		1999
University of Utah	Technology Innovation Grant Program	$300,000/yr	No	1993
University of Washington		Established with $250,000	No	For several years
University of Wisconsin–Madison	1. Industrial and Economic Development Program	$900,000/yr	Yes	1973
	2. Robert Draper Technology Innovation Fund	$400,000/yr	Yes	1981

Case Study 1: Industrial and Economic Development Research Program

The Industrial and Economic Development Research Program (I&EDR) is a state-funded program that has been in existence since 1965. Its purpose is to fund campus projects that will promote economic growth in the state of Wisconsin. The state statute reads: "The board of regents shall award industrial and economic grants to fund industrial and economic development research projects and outreach activities."

Management of the program has varied over the years (for example, at one time there was no formal call for proposals, evaluations were done by very few people, and individual grant amounts were as high as $100,000 and often awarded for two to three years).

Today the program has a one-time call for proposals each fall. Faculty and academic staff researchers with principal investigator status are eligible to compete. A review committee that includes faculty members, who are selected according to their area of expertise, evaluates proposals for technical merit (40 points). Proposals are also evaluated for commercial potential (60 points) by a review committee composed of industry-experienced staff members in the office of University-Industry Relations (UIR). Normally, review committees are composed of five to seven members.

As implied by the fact that 60 out of 100 points are allocated to the commercial evaluation, industrial and economic relevance to the state of Wisconsin is by far the most important factor. Indeed, it is the strength of this section that determines primarily whether a program will be funded. Letters of support from industry, matching funds, in-kind contributions, evidence of intellectual property consideration, industrial involvement, and the proposer's plan to transfer technology to the commercial sector are all-important to the final decision.

I&EDR provides funding for up to $50,000 for twelve months of effort, with typical awards ranging from $20,000 to $40,000.

A survey was conducted to determine the outputs of this program. The I&EDR survey covered the period fiscal years 1986–95. The survey included questions such as: number of inventions produced from project, interactions with the private sector, implementation by the private sector, companies formed, consortia established, students trained, publications, private-sector funding subsequent to grant, government funding subsequent to grant, and, overall value of grant to research effort.

The authors attempted to survey all principal investigators. Of the 174 I&EDR projects funded during the survey period, responses were received on 126 projects (72 percent), and the statistics are based on those responses.

Results are discussed below and presented in table 2 in combination with responses to the Robert Draper Technology Innovation Fund program, which follows.

Case Study 2: Robert F. Draper Technology Innovation Fund

Established in 1981, the Robert F. Draper Technology Innovation Fund (TIF) is supported by funds derived from royalties provided to the university by its patenting and licensing agency, the Wisconsin Alumni Research Foundation (WARF). The purpose of the TIF program is to support additional research often necessary to achieve the broadest possible patent claims and secure licensing terms from the commercial sector. Unlike the I&EDR program, there is no requirement that the project benefit the state of Wisconsin.

As with the I&EDR program, the structure of the TIF program has varied over the years, but today the minimum requirement to qualify for a TIF grant is that a patent disclosure must be on file with the university. Proposals are accepted from faculty and staff researchers for consideration at any time and are evaluated on their scientific and technical merit, patenting, licensing, and commercialization potential by people from UIR and WARF, with faculty technical reviewers being used on an as-needed basis. Projects are funded to flesh out patent claims, develop prototypes, produce materials for testing by industry, or to generate additional data that will increase a technology's patenting and licensing potential. The primary determinant controlling fundability is the extent to which the work will support patent and licensing potential and increase commercial impact.

Grants are awarded for one year and typically range from $2,000 to $40,000. Similar to the I&EDR, a survey was performed to determine the outputs of this program. The TIF survey covered fiscal years 1986–96.

The survey paralleled that of the I&EDR, including questions such as: number of inventions produced from projects, interactions with the private sector, implementation by the private sector, companies formed, consortia established, students trained, publications, private-sector funding subsequent to grant, government funding subsequent to grant, and, overall value of grant to research effort.

Results discussed below and shared in table 2 are based on 28 of 32 funded projects (88 percent).

I&EDR and TIF Results

The data presented in table 2 for both programs show a combined 7.7:1 leveraging of funds invested, indicating success in achieving the funding objectives. In addition, 69 percent (22 of 32) of the TIF projects and 22 percent (39 of 174) of the I&EDR projects have been implemented by the private sector. Seventy-eight percent of the TIF projects and 26 percent of the I&EDR projects generated additional inventions. The programs also have resulted in the formation of new companies, the establishment of consortia, and the training of hundreds of students. Almost half of the TIF respondents used words such as "vital," "critical," "essential," or "instrumental" in describing the usefulness of the funding.

Others made the point that quick access to even small amounts of gap research dollars was crucial to the success of their research programs. For the years 1993 through eight months of 1999, royalties of $360,774 were reported on licenses based on inventions that arose from the TIF program (excluding royalties from one program that were so large as to skew the results). Since these are from licenses that are relatively new, these royalties should continue to grow.

What is encouraging is that both of the UW–Madison programs, though very applied in their orientations, have been successful in generating additional federal funding: 5.6 federal dollars for every dollar of I&EDR funding, and 5.3 federal dollars for every dollar invested by TIF. Thus supporting the premise that results of applied research can be used to generate additional federal funding.

What Works?

A tangential outcome to the survey was a request by university technology transfer managers to hear more about the dos and don'ts to administering a program to provide gap funding. The common theme was, tell us what works. Shared below is a list of helpful tips.

1. *Don't allow the process to become politicized.* It is probably inevitable that pressure will be exerted to fund particular researchers for reasons that have little or nothing to do with the merit of their proposals. The temptation to bend to such pressures must be avoided at all costs. Strict adherence to a policy of independent and confidential merit reviews by several individuals is essential.
2. *Do include both technical and commercial components in the evaluation process.* A scientific technical review is necessary to ensure that the program only funds sound research. Enlisting faculty members to serve

Table 2

Outcome Results of the University of Wisconsin–Madison Industrial and Economic Development Research Program and Robert Draper Technology Innovation Fund Gap-Funding Programs 1986–96.

	I&EDR	TIF	Combined
Amount granted over survey period	$2.5 million[a]	$1 million[b]	$3.5 million
Number of projects funded	174	32	206
Number of respondents	126	28	154
Students trained	>1,097	>65	>1,162
Publications	308	>125	>433
Federal dollars received as direct result of grant	$14.1 million	$5.3 million	$19.4 million
Industrial dollars received as direct result of grant	$4.7 million	$2.4 million	$7.1 million
Total funding generated as direct result of grant	$18.8 million	$7.7 million	$26.5 million
New companies formed	9	7	16
Consortia formed	8	0	8
Number of projects with results implemented by private sector	39	22	61
Number of projects that generated intellectual property	45 (26%)	25 (78%)	70 (34%)
Number of projects with results licensed by private sector	N/A	15	15
Royalty generated during fiscal years 1993–96	N/A	$0.4 million	$0.4 million
Leveraging[c]	$7.5:1	$8.1:1	$7.7:1

a Includes all funds distributed over years, whether or not principal investigator responded to survey.

b This amount does not include five grants totaling $126,000 that were awarded at various times to one particular investigator because these projects resulted in such a large (multimillion dollar) royalty stream that including either the awards made or the revenue received would distort the results.

c Includes total of royalties, industrial, and research funding received divided by amount granted over the funding period.

as reviewers is always a good practice because it contributes to the credibility of the program and decreases the likelihood of allegations that university funds are being used to support substandard research. A review of commercial potential, on the other hand, is best done by individuals who specialize in technology commercialization and are attuned to industrial needs, such as staff members of the technology transfer office and experts from the commercial sector.

3. *Do favor smaller grants over larger ones.* Although faculty prefers larger grants, smaller grants allow for the funding of more programs. It is not unusual to cut a requested supply budget in half (often without any complaint from the investigator). Funds in support of travel to conferences and large capital expenditures are reviewed with a critical eye. The program has a much greater demand than funds available.
4. *Do give preference to one-year projects.* Projects lasting less than a year are problematic because graduate student assistantships are usually allocated in at least one-year blocks, and postdocs certainly cannot be expected to commit to a project for less than twelve months. Conversely, projects that require more than a year to achieve their milestones are probably too basic in their orientation.
5. *Do advertise the program widely in the university community.* If the existence of the program is known only to a select few, there is a real risk that worthy projects will be missed.
6. *Do set realistic expectations.* The survey of university gap-funding programs noted above also uncovered several programs that had been discontinued because the university's expectations were unrealistic from the outset. For example, one program was launched with $600,000 in seed money, and then abruptly terminated only three years later because it hadn't generated the expected 30 percent return in royalties alone. Considering that it can take ten to fifteen years to commercialize a technology, such short-term thinking is unfortunate, especially when it is accompanied by a too-narrow focus in defining what constitutes success. In the long run, universities may well discover that the most important benefits from gap funding go beyond royalties received (see table 2).

And finally, one lesson learned from several years of administering gap-funding programs is this: All decisions must be made on the potential for return on investment—financial and otherwise.

Gap Funding Is Important

In summary, the experience of the UW–Madison, documented through the case studies presented in this paper, supports the premise that gap funding can provide tremendous support to technology transfer efforts.

It is also noteworthy that one institution that did have significant data on the outputs of its program in response to the survey also supports this premise. Specifically, the University of British Columbia reported[2] that twenty-eight commercial licenses and twenty-one spin-off companies have resulted from fifty-six technology projects that were funded during the first six years (1989–95) of its Prototype Development Program (PDP) at a total project support cost of $1.84 million. The new companies in turn generated $19 in government ($4) and private investors ($15) for every $1 invested in them by the PDP. Finally, the vast majority of new ventures chose to locate in British Columbia. The latter finding is similar to that observed with spin-offs having close ties with UW–Madison[3] and for many other academic institutions reporting spin-off activity.[4]

It is important to document positive outcomes of these programs. And, in so doing, administrators should consider returns beyond royalties. For example, the number of students trained, consortia started, new companies formed, and research dollars generated are all important measures of success. However, it should be pointed out that it is not possible, or perhaps even desired, to compare outcomes of various university gap funding programs since there are no universally accepted standards of measurement. Further, the goals, design, and implementation of the various programs also differ and outcomes are normally assessed based on the importance assigned by the institutions to specific outcome metrics.

There is a need to determine if these gap-funding programs are adding the value required to move university technologies down a developmental path. If positive outcomes are established, perhaps this would help additional universities to expand or develop such programs of their own. At this time, a meaningful interinstitutional evaluation of outputs is hampered by the fact that so few universities have tracked the downstream benefits of their programs. Therefore, the authors encourage technology transfer managers to assess the outputs of their gap funding programs.

It is interesting that more institutions have not developed similar funding systems internally (evidenced by nineteen reporting programs of more than

thirty surveyed). It is also recognized that states may have alternate programs that serve a similar purpose and/or that funding by venture capitalists may help to fill this gap. Acknowledging these other possibilities, the focus of this paper is on those programs established internally by the institution in support of gap funding. Our interest is that, as more managers gather data on the output of their programs, additional institutions will value the importance of investing funds internally to fill the gap and enhance the flow of technology from universities to the private sector.

Notes

[1] The authors express their appreciation to Donna Ford and Jane Sherwood of the UIR staff for their assistance in collecting and tabulating the outcome data reported in this article. Also, the authors acknowledge the valuable commentary on the manuscript provided by Ann Roberson, Esq., president of the University of Tennessee Research Foundation. Finally, we thank all of the survey responders for their cooperation in providing the university specific data shown in table 1.

[2] For a full report on the UBC Prototype Development Program, see www.uilo.ubc.ca/.

[3] P.Z. Sobocinski, *Creating High-Tech Business Growth in Wisconsin: UW–Madison Technology Transfer & Entrepreneurship* (Madison, Wis.: The University of Wisconsin, 1999).

[4] Association of University Technology Managers 1999 Survey, see www.autm.net/surveys/99/survey99A.pdf.

A Review of Best Practices in University Technology Licensing Offices

Michael F. Allan

Abstract

Many methods and modes of operation in the technology licensing office of major universities are similar. Reputation of the institution and quality of the faculty are important factors in the effectiveness, by any measure, of the technology licensing office. Small but important distinctions have been observed from one organization to another. Each characteristic must be considered in the macro- and microenvironments in which the TLO functions. Together, these conclusions provide the basis for recommendations for new and existing TLOs to consider.

Introduction and Methodology

The technological orientation of the United States has in no small way set the stage for the transfer of technology out of universities. A variety of federal, state, regional, and local conditions have also had an impact on this dynamic, such as enterprise development zones, tax incentives, and other programs.[1]

In the corporate sector, years of downsizing have led to the willingness of more companies to consider outsourcing in general and technology licensing in particular. Licensing-in is seen increasingly as complementary to developing know-how in house and can be an attractive option in the make-vs.-buy decisions characteristic of corporate business-development strategies.

In consideration of establishing a technology licensing office (TLO) in the United States, the Japanese External Trade Organization engaged First Principals Inc. to report on characteristics of TLOs in major research universities. FPI was asked to consider organizations on the East Coast, where JETRO had decided to locate.

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From a selection of more than two dozen TLOs, FPI based its reporting on conversations with TLO representatives and public information about TLO operations.[2]

In support of this, information was collected and compiled from a variety of other organizations, including universities, U.S. government technology transfer institutions, technology commercialization firms, and law firms.[3]

In addition, recommendations presented are derived from AUTM annual survey data, TLO and organizational Web sites, third-party and/or anecdotal resources, and FPI-compiled information regarding technology commercialization processes.

As part of the final report, FPI provided a summary of each interview conducted. A format was developed to consistently capture key information and profile each TLO. Profiles also presented a summary of the interview.

The report was structured around five major topics:

- *Operations:* This area focused on methods and processes used in the technology commercialization process by TLOs selected for study and included discussion on operational procedures, use of outside patent counsel, greatest challenges, and other characteristics and practices of each TLO.
- *Economic impact:* This section considered economic metrics for technology commercialization and licensing such as numbers of patents, licenses, licensed products, commercialized products, and income generated. Contributions to local businesses or in establishing new businesses were also explored. (Much of the raw data for this section is contained in the profile summaries, which are not provided in this paper, and drawn from the AUTM survey.)
- *Commercialization initiatives:* This section includes information on government efforts to facilitate technology transfer, university-industry collaborations, and legal or policy incentives, such as accounting or tax incentives, if any.
- *Success stories:* Specific home runs achieved by university TLOs are interesting but exceptional cases. This section generally discusses broader incubation issues relevant to transferring technology from a university to a business entity.
- *Trends and issues:* In this section, current realities of the technology transfer professional and those faced by TLOs are examined, especially with regard to how the issues impact on philosophical and operational practices in technology commercialization.

For the purposes of this paper, significant observations gleaned from the study will be presented for each of these topics, followed by recommendations with respect to establishing a TLO based on best practices observed in the course of the study.

Operations

For the purposes of this study, the major topics considered in technology transfer are:

- disclosure of inventions,
- record keeping and management,
- evaluation and marketing,
- patent prosecution,
- negotiation and drafting of license agreements,
- management of active licenses.

That is, university technology transfer is mainly a system of disclosure, patenting, licensing, and enforcement of patents and licenses.

From interviews with TLO professionals and public information such as that which is available on Web sites, the data indicate a reliance on the use of external patent law firms to aid the patenting process. However, few other functions appear to be outsourced. Echoing this is the observation of one of the respondents who said that hundreds of thousands of dollars are often devoted to patenting and legal counsel costs, yet almost nothing is set aside for marketing the patents that result.

Formal, proactive technology marketing programs are highly varied in the TLOs surveyed. Some TLOs do very little active marketing. Available technologies are listed only selectively on their Web sites. One respondent stated that in his office, they literally wait for the phone to ring.

In general, both large and small institutions market their intellectual properties primarily through Web-based posting services, university home pages, and through the AUTM Web site. In spite of competition from many corners—corporate out-licensing campaigns, consultants, commission- and fee-based companies, and high-profile Web-based services—scant evidence supported the idea that TLOs are increasing their current level of marketing. As a representative of a large TLO stated, "Why do we need to market our

technologies when everything is on our Web site?" These practices seem particularly counterproductive in the case of some schools, which would require extra efforts to gain the same level of attention as top-tier schools. Smaller TLOs typically lack sufficient human or financial resources to overcome this barrier.

The case-management style, sometimes referred to as cradle-to-grave approach, is commonly practiced in many of the TLOs studied. In this system, typically one person is responsible for the actions required for a particular case, from disclosure through patenting, and sometimes beyond. This approach offers the advantage of centralizing awareness and coordination with all major aspects related to a particular intellectual property. The practice is especially common in larger offices. However, this management style requires the talents of very skilled individuals with experience in processes ranging from invention disclosure through commercialization. The breadth and depth of these processes usually leaves little time for proactively promoting the opportunity. Consequently, few institutions have staff dedicated specifically to marketing programs for their institutions' intellectual property.

Staffing changes in TLOs around the country do not seem to be addressing this trend. Advertisements for available positions and anecdotal evidence support an emphasis on subject background, rather than functional experience, for example.

Several organizations in this study were found to place substantial effort in training faculty in patenting and the innovation process. However, the extent to which this enhances the measurable outcomes of TLOs has not been evaluated here. Of the institutions that were studied, TLOs with long-standing operations seemed to draw more from years of precedence and reputation to maintain and enhance the technology transfer process.

Surrounding the methods and processes stand university policy and the mandate of Bayh-Dole. These policies increasingly focus on addressing how inventions might be developed for the economic benefit of local communities.

Economic Impact

Without question, the economic impact of university licensing activities is substantial. In 1999, the commercialization of academic research resulted in more than $40 billion in economic activity, which, in turn, supported more than 270,000 jobs, according to AUTM.[4]

According to the AUTM survey, business activity associated with sales of products from academic research is estimated to have generated $5 billion in tax revenues in the United States at the federal, state, and local levels in 1999. More than 340 new companies based on an academic discovery were formed in 1999, with 82 percent of them operating in the academic institution's home state. Columbia University earned revenue of $89.1 million in 1999 from patents, ranking it in No. 1 in the country.

From a review of the information compiled and FPI experience, it is evident that there is little correlation between budgets, number of patents, or other quantitative measures and the degree of success a TLO will have in terms of generated income. The dual objective of fulfilling institutional objectives of service and performing as a profit center is, in many instances, an unattainable goal. According to several interviews, this goal can often lead to a high degree of frustration.

Consider for instance Columbia University, which has often appeared at or near the top of AUTM's survey in terms of licensing income generated. Yet, it was granted an average of only 34 patents per year from 1994 to 1998.[5,6]

Yale University reviewed its 850 invention disclosures from 1982 through 1996 and learned the following:

- One percent (10 of 850) of total disclosures led to 70 percent of $20.4 million received,
- Four percent (33 of 850) of disclosures accounted for 90 percent of the total licensing income,
- Eighty-eight percent (748 of 850) of disclosures generated less than $10,000 each, the approximate cost for processing one invention disclosure.[7]

These examples suggest that a key focus for TLOs is to decide how to allocate development efforts, since not all disclosures offer equal promise of success.

Commercialization Initiatives

The impact of economic and health benefits on local and national economies arising from university technology transfer leads to the conclusion that the Bayh-Dole Act is one of the most successful pieces of economic development and job-creation legislation in recent history. It is clear that this act is also one of the most powerful influences over how technology transfer is conducted at universities today.

Proactive customer-relations programs and management of TLOs' constituent relationships are gaining attention. Several institutions surveyed are implementing a variety of means to foster an entrepreneurial environment. These programs are often directed far beyond inventors or likely inventors. Outreach to the community in which the university resides, particularly in the case of state-funded institutions, is on the rise. This trend is more apparent at universities not ordinarily considered in the top tier of schools as ranked by criterion typically measured by AUTM surveys.

For example, one university studied hired an outside firm to measure customer satisfaction with its TLO. Several TLOs reported holding annual recognition events, such as banquets or luncheons, for inventors who have been granted patents during that year.

Written policies pertaining to most aspects of technology transfer are a real benefit and are, for the most part, thorough and well-done. They also tend to be readily available through the Internet. By extrapolation, the easier it is to understand the policies, the more likely that they will be followed. Although not specifically observed in the course of this study, it would seem to the author that decoding the policies would facilitate their use. That is, pocket guides, condensed versions, summaries, and other surrogates are owed consideration to ensure that all TLO stakeholders are aware of and maintain these policies. This would complement the in-depth training being given by some TLOs to faculty, as previously noted.

Numerous educational offerings are available for learning about the process of technology licensing from a number of organizations in the non-profit and for-profit sectors. AUTM's course offerings demonstrate a strong lead to facilitate this learning.

The Council on Governmental Relations is an association of research universities that deals mainly with policies and technical issues involved in the administration of federally sponsored programs at universities. COGR has also prepared a useful tutorial and overview of technology transfer in the United States.[8]

Success stories

Cities such as Cambridge, Massachusetts, and Palo Alto, California, see new companies and jobs springing up out of the universities in their communities. State governments are setting aside money specifically to fund technology transfer offices and company incubators with their universities. Local communities are also getting involved by backing organizations that foster university-based economic development.

Even on an international scale, the phrase *Bayh-Dole* is heard frequently in Japan and Germany as their educational ministries seek to emulate the technology transfer system as practiced by U.S. universities.[9]

University technology transfer has helped to spawn new businesses, create industries, and open new markets. It seems likely that 2002 will see the formation of at least 300 new companies, based on extrapolations from FY1999 AUTM data.

Moreover, many new products and services that improve our quality of life can be shown to arise from university research. From new cancer treatments to faster modems, from environmentally friendly metal processing to beautiful flowering plants, technology transfer from academic institutions is enhancing the way we live and work.

Formal technology development and business incubation programs are common to all universities surveyed. One of the earliest success stories is Research Triangle Park in North Carolina. RTP was created through the joint efforts of several research universities, numerous business development and government interests, and the availability of millions of acres of real estate. These forces combined to create the critical mass necessary for its formation. Although RTP benefits from more than forty years of operation, its success may be seen as symbolic of technology transfer in the region. (Success rates of business-based incubators and university-based incubators are debatable and involve issues beyond the scope of this paper.) Nonetheless, the degree of collaboration among major participants then is a model to embrace today.

Putting aside the arguments in support of various models of incubation, the rule of thumb still holds: Only one in ten new ventures succeeds.[10]

One might expect that this truism would also apply to technologies guided by even the most effective TLOs. This reality may need to be revisited occasionally to reign in overly optimistic views of politicians and high-level administrators.

Notable observations that amplify this conclusion have been made by Nelsen: "The direct economic impact of technology licensing on the universities themselves has been relatively small (a surprise to many who believed that

royalties could compensate for declining federal support of research). Although a very few, and highly visible, blockbuster inventions such as the Cohen-Boyer gene-splicing patent from Stanford University and the University of California, the fax patent [sic] owned by Iowa State, and the cis-platin patents of Michigan State University have made tens of millions for universities, most university licensing offices barely break-even."[11]

Trends and Issues

A significant best practice described to FPI by several respondents relates to the practice of periodic staff meetings and formal and informal discussions of cases under management by TLO staff. At larger universities such as Harvard and the Massachusetts Institute of Technology, these war stories serve to emphasize details that create an important internal knowledge base. Sharing of this collective experience provides an array of how-to advice and extremely valuable insight, especially for junior members of the TLO teams.

Cogent communications would seem especially helpful in unraveling complex economic-development issues. From FPI's survey and a growing body of published literature, universities are concerned increasingly with technology-based economic development. Both private and state-funded universities are seen to be active in networks of state-sponsored initiatives. A variety of programs tout capabilities offered by individual universities within the state and the extent to which they contribute to the economy of the state. TLO staff members are often major players in these programs.[12]

From interviews and nonproprietary information about TLO operations gathered in the course of this study, observations have been made regarding the background of TLO staffs and the extent of experience among staff with complex business-development issues. One implication is that the later stages of technology commercialization should receive more emphasis by TLO operations.[13]

Conclusions

Many issues, major and minor, have emerged from this study of TLOs. Primary conclusions are summarized below.

- Pressures from public-sector agencies to commercialize technology, especially with respect to starting companies to create jobs in local economies, are raising complex issues.
- Personnel issues surfaced which may portend new trends with respect to recruiting and retaining TLO staff.[14,15]
- Bayh-Dole and university policies create a precarious balancing act between the mandate to provide service to all clientele equally and the goals to commercialize technologies of greatest potential.

Recommendations

Creating a TLO from the ground up involves consideration of complex and multidimensional issues. It is critical to draw from the experience of a range of networks and individuals in the technology transfer and commercialization business, on multiple levels. These resources include universities, nonprofit organizations, professional associations, commercial firms, consultants, financial institutions, government agencies, and venture-capital groups.

From the data arising from this study and the collective information available to the author, the following five-point strategy has crystallized to address these issues and establish an effective TLO.

1. *Capitalize on potential success quickly, by means of practices such as those exhibited by Yale's Office of Cooperative Research.*
   - Establish specific strategies to seek new inventions early.
   - Examine a large number of disclosure opportunities quickly.
   - Review and document probability of finding licensees through proven assessment techniques.
   - Follow up with thorough review to select the strongest candidates for success.
   - Ensure that sufficient time is spent on the inventions deemed to have the most potential for success.[16]
2. *Broaden the base of resources available to staff to enable maximum performance levels by maintaining awareness of external organizations in for-profit and nonprofit sectors.*
   - Survey a variety of law firms, technology marketing organizations, and professional societies for their potential to provide labor-saving services.
   - Consider appropriate staffing and resource levels, and address policies devoted to recruiting and retaining staff, including alternative compensation schemes.
   - Monitor developments in legislation that have an impact on available funding assistance.

3. *Manage expectations of all stakeholders by establishing effective tools and communications systems.*
   - Attain buy-in throughout all levels of the organization.
   - Map a clear mission and develop measurable objectives.
   - Facilitate periodic meetings, educational seminars, and training sessions for inventors and staff. Subjects may include business news, innovation theory, policy and organizational changes, information resources, etc.
   - Develop thorough guidelines and concise, easy-to-understand policy surrogates to ensure that procedures are maintained and followed, both inside and outside of the TLO.
4. *Increase familiarity with business-incubation issues and include them in the scope of TLO policies and operations.*
   - Study regional success stories such as Research Triangle Park and others.
   - Solicit observations from other university-affiliated operations.
   - Consider membership in organizations such as the National Business Incubator Association and Association of University-Related Research Parks.
5. *Make the most of networking opportunities, training programs, and other membership benefits. Among many organizations, the following are particularly relevant to the TLO professional.*
   - AUTM regional meetings and programs of study provide intensive and cost-effective benefits for new and experienced members of the technology transfer community.
   - AUTM's annual licensing survey provides comparison data to enable benchmarking. A summary is available free on AUTM's Web site.
   - The Licensing Executives Society is a professional organization that deals with all aspects of technology licensing. Membership is from corporate and university ranks. LES provides excellent training and continuing education programs, in addition to opportunities to participate in issues relative to marketing, ethics, and international aspects of technology transfer, to name a few.

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Notes

[1] Two examples are Ohio's Technology Investment Tax Credit program at http://www.odod.state.oh.us/tech/titc and New York State Office of Science, Technology & Academic Research program at http://www.nystar.state.ny.us/home.htm. NYSTAR has adopted the mission of making New York the leader in high-technology academic research and economic development.

[2] In this paper, specific comments from individuals interviewed have not been divulged. Information provided is of a general nature and/or available from public sources.

[3] A premise of this study is that the variety of sources of information utilized provides a useful basis upon which university TLOs may draw in consideration of their own practices.

[4] Association of University Technology Managers Inc., *AUTM Licensing Survey: FY 1999*, c2000.

[5] Zacks, Rebecca, "The TR University Research Scorecard," *Technology Review*, July/August 2000 (http://www.technologyreview.com/articles/scorecard0700.asp).

[6] Number of patents issued is a popular yet contentious metric. The AUTM survey identified 2,718 issued U.S. patents in 1999 for 77 universities and 14 institutions in the U.S. Of the 91 TLOs, 29 met or exceeded the average of 32.1 patents (34 percent). A walk on thinner ice is encountered in the case of gross licensing income received. In fiscal year 1999, 139 university TLOs generated approximately $675.5 million, equating to an average of about $4.86 million per TLO. Of the 139, 24 exceeded the average (17.3 percent). It is not the intent of this study to deduce a significant relationship between the two measures. It would be of interest, at least to this author, to consider research expenditures of corporations and universities vs. patents issued to each for a dollars-per-patent indicator.

[7] See the Yale Office of Cooperative Research home page, in particular, Senior Director Gregory E. Gardiner's 1997–98 report at http://www.yale.edu/ocr/images/docs/ocr_report_96-98.pdf.

[8] Council on Governmental Relations, *A Tutorial on Technology Transfer in U.S. Colleges and Universities*, http://www.cogr.edu/techtransfertutorial.htm, c1999.

[9] See Reference 11.

[10] Volkmar, Susan, "Incubating More than Just Eggs: North Carolina's Research Triangle Park," www.biomednet.com/hmsbeagle/55/notes/adapt, posted May 28, 1999, Issue 55.

[11] This is a personal viewpoint by Lita Nelsen, director of Massachusetts Institute of Technology's TLO (http://web.mit.edu/newsoffice/tt/1998/aug26/nelsen.html), reprinted from *Science* 279:1460–61 (No. 5356, 6 March 1998). The author has been informed from a source close to the Iowa state TLO that the patent is not a fax patent per se, but is a method used by the fax machine that increases its speed.

[12] To help address the challenges and reap the benefits of technology-based economic development, TLOs ought to investigate the State Science and Technology Institute. Located in Westerville, Ohio, SSTI (http://www.ssti.org) is a national, nonprofit organization dedicated to improving joint government-industry programs that encourage economic growth through the application of science and technology. SSTI provides information about cooperative technology programs and funding sources, holds conferences and workshops, conducts policy research and impact analyses for federal and state programs, and facilitates communication and cooperation among and between state and federal science and technology programs. The *SSTI Weekly Digest* is an excellent and free resource published by the SSTI to fulfill this mission.

[13] It is the opinion of the author that the range of issues confronted by TLOs has broadened, and this adds significantly to the challenges faced by TLO professionals. More professors are aware of and motivated by entrepreneurial incentives and more localities are calling on their universities to contribute to their community's economy, for instance. Company formation is a relatively new challenge for the TLO; one that brings a number of complex issues to bear that may not have been anticipated. Therefore, the responsibilities of TLO staff are also stretched. Owing to the difficulty of attracting and compensating employees with talents to master all such relevant areas, it is recommended that consideration is given to partnerships with other TLOs, making use of consultants, and development of other external resources and networks.

[14] One significant manifestation of these issues that was reported to the author in several instances is the incidence of employee turnover, especially at director or associate director levels. Interviews also suggest that the issue of incentive-based compensation for TLO staff simmers on the back burner. Two of the barriers facing implementation of alternative compensation programs are how to involve all levels of employees and complex conflict-of-interest dynamics.

[15] More than 24 help-wanted ads were received by the author in the last nine months of 2001 (to say nothing of observed heresay), which spoke to staff positions open in other TLOs across the United States. According to the advertisements, marketing-related experience is rarely a prerequisite qualification. Further, several conversations between the author and TLO personnel indicate that implementation of policies and practices are significantly deferred by the hiring delay. In multiple instances, the delay between publication of the available position and hiring the person to fill it can be shown to have exceeded six months.

[16] In a perverse extrapolation of Pareto's Law, it is easy to imagine how 80 percent of one's efforts might be directed to a technology disclosure that would more appropriately receive 20 percent of one's attention. The experiences at Yale's Office of Cooperative Research seem to bear this out. Statistics referenced in the text, and the processes used to develop and implement new best practices, are gleaned from the OCR Web site. In particular, Senior Director Gregory E. Gardiner's 1997–98 report is instructive. See http://www.yale.edu/ocr/images/docs/ocr_report_96-98.pdf. FPI's client indicated that Yale was one of the universities in which they were particularly interested.

Technology Licensing Meets Medical Privacy: Coexistence or Collision Course?

Richard J. Kordal and Joseph D. Fondacaro

Abstract

As biomedical research delves deeper and deeper into the human genome, medical privacy has become an ever-increasing focus. A host of entities, from the federal government to local health-care providers, are shifting their attention to this important issue. Where collection of human tissues and patient information become research tools, biomedical research institutions, physicians, and researchers must be aware of new federal regulations, local guidelines, and ethical standards of the genetic age. Likewise, these issues can and will impact the technology transfer process. This article is intended to shed some light on this subject and alert the technology transfer professional to these issues.

Not to be left out of the potentially lucrative commercial opportunities that Wall Street has favored recently (for example, the deCode Genetics Inc. initial public offering raised $198.7 million), many universities are beginning to explore ways to benefit financially from mining genomic data residing in tissue banks or derived from research. In some cases, blood samples and tissue biopsies taken at the time of surgery are stored and utilized later for genetic research studies, the information from which could be used to develop novel pharmaceutical and gene therapies. University medical schools and biomedical research institutions can potentially license this information to pharmaceutical and biotechnology companies, thus providing an avenue for a multitude of new therapeutic modalities to treat many types of diseases. As the value of population-derived genetic information grows among biomedical research institutes and their faculties, it can easily be

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visualized that the demand for this type of information will grow proportionally. Some pundits have speculated that this might be the beginning of a very large trend.[1]

Although now abandoned, one attempt by Boston University is an example of such an endeavor. Framingham Genomic Medicine Inc. was to be established to analyze more than fifty years of data that had been collected within the federally financed Framingham Heart Study.[1,2]

Initiated in 1948, the study enrolled 5,209 patients living in Framingham, Massachusetts, to identify cardiovascular-disease risk factors. In 1971, 5,135 additional patients were added to the study, representing the offspring of the original cohort. Since 1971, this study has been expanded to include genetic factors contributing to health and disease, not only in the cardiovascular subspecialty, but also in aging, osteoporosis, arthritis, pulmonary disorders, deafness, diabetes, and neurological disorders. In the 1980s, the researchers began collecting, storing, and analyzing blood and extracting DNA samples.

Fred Ledley, M.D., the would-be chief executive officer of Framingham Genomic Medicine, indicated that the intent was to digitize the study's voluminous paper records and use state-of-the-art bioinformatic tools to examine tens of thousands of different genetic landmarks on a participant's DNA so as to integrate genetic, clinical, and behavioral data for analysis of association between clinical and human-genomic information. The plan was to continue to make the raw data available essentially free to academics but to charge for-profit companies a fee to access the company's analyses.

According to newspaper reports,[3, 4] the main stumbling block was the length of time the enhanced data would have remained proprietary. Officials at National Institutes of Health's National Heart, Lung, and Blood Institute (NHLBI) wanted the enhanced data placed in the public domain too quickly for the company. It was the company's view that, in order to maintain the value of the new database to their paying customers, they needed more time to keep it secret than NHLBI was willing to accept. Despite efforts by the officials to resolve this issue, the negotiations ended without a resolution, prompting Boston University to disband the company.

Notwithstanding the potential boon to medical science and commercial interests that this type of data represents, many expressed their unease about the ethics of licensing and commercializing data originally collected

for noncommercial purposes. Despite assurances that the confidentiality of the study's participants would have been maintained, legal experts were concerned about the adequacy of the safeguards and whether the company would have fully conformed to state and federal medical privacy mandates. The potential for a breach of confidentiality and its legal ramifications were also issues for the parties. Despite these concerns, it is interesting to note that, by all accounts, the ethical and legal issues in the Framingham Genomic Medicine case were worked out satisfactorily.

As more and more universities become involved in collecting and archiving medical information with an eye toward licensing, technology transfer offices around the country are faced with confronting these unique privacy issues for the first time. Some aspects of these new issues are surprisingly fundamental. One question that immediately arises is, Who *owns* the patient's medical information—the patient or his or her physician? In many states, courts recognize a property interest of the health-care provider in the original medical records (e.g., blood-test results, x-rays, etc.) regardless of who paid for the tests (patient, insurance company, or, in the case of an indigent patient, the hospital).

If, however, the test results were collected during a clinical trial or research study funded by a corporate sponsor, the sponsoring institution may not own the data. It all depends on the terms of the clinical-trial contract. Generally, most academic institutions require that they own the data, but grant the sponsor a nonexclusive license to it. To compound matters, there are situations where the medical information includes medical images such as an x-ray or MRI. Some contend that this information may be protected under copyright laws. Irrespective of ownership, there still are moral and ethical (and increasingly legal) obligations to protect the confidentiality of the data and the patient's rights.[5]

The matter becomes emotionally charged when one considers human specimens (e.g., a person's excised tissue), particularly in light of the now celebrated *John Moore v. The Regents of the University of California* lawsuit in California.[6] Moore's spleen was surgically removed for medical reasons. Prior to surgery, Moore signed the hospital's usual consent-to-care form. Unbeknownst to Moore, his doctor gave his spleen to a biotech firm. The firm subsequently used the tissue to develop a highly profitable immortalized cell line that produced chemical compounds called lymphokines, with great

commercial potential for therapeutic purposes. The physician did this without first obtaining Moore's informed consent for this use.

Later, when Moore learned of this, he filed suit against his doctors, the university, a biotech company, and a pharmaceutical company. In his suit Moore alleged thirteen causes of action, including counts of conversion of property (tort equivalent of theft) against his doctor, the biotech firm, and the pharmaceutical firm and counts of lack of informed consent and breach of fiduciary duty against his doctor only. The case ultimately worked its way to the California Supreme Court, which, on the matter of conversion, found in favor of the commercial defendants, but held that the lack of informed consent and breach of fiduciary duty counts could be pursued against the physician. It was the court's viewpoint that Moore lost his property interest in his tissue in much the same way a person does when they discard trash, finding, in addition, that the public policy favoring medical research argued against recognition of a patient's property rights under a conversion theory.[5] The matter never went to trial, but was instead settled out of court.

On November 3, 1999, the United States Department of Health and Human Services proposed regulations to implement the privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA).[7] After a comment period, the final rule was published in the Federal Register on December 28, 2000,[8] and became effective on April 12, 2001, following a second comment period. Large organizations were given until April 12, 2003, to comply, while small health plans were given until 2004. The regulations will control the disclosure of personal medical information among health-care providers—specifically health plans (e.g., insurance companies), health-care clearinghouses (e.g., firms that process medical claims), and health-care providers (e.g., physicians, hospital laboratories). HIPAA regulations also establish a basic level of protection for personally identifiable information. It is important to note, however, that the federal regulations will not preempt stricter state laws that provide greater levels of protection.

One of the objects of the HIPAA rules is to make the exchange of protected health information relatively easy for purposes of delivering health care. Under the rules, covered entities could use or disclose protected health information for treatment, payment, and health-care operations providing they first receive the patient's consent. Presumably consent will be obtained at the time medical service is sought. In order to disclose the use

of protected health information to noncovered entities, they would first need to receive the individual's authorization.

The rules make a distinction between consent and authorization. The rules permit disclosure of health information without individual authorization for certain national priority activities such as research, oversight of the health-care system, public health, to identify the body of a deceased person of the cause of death, judicial and administrative proceedings, limited law-enforcement activities, and a few others.[9] In §164.512(i) of the regulation, the rules stipulate, however, that before protected information can be released for research use, a waiver from authorization must be obtained from an independently approved privacy board or institutional review board (IRB) following the so-called common rule governing IRB review procedures.

The waiver must satisfy the following criteria: (1) disclosure involves no more than minimal risk to the individuals, (2) the waiver will not adversely affect the rights and welfare of the individuals, (3) the research could not practicably be performed without the waiver, (4) the research could not practicably be conducted without the information, (5) the research is of sufficient importance to outweigh the intrusion of privacy, (6) there is an adequate plan to protect identifiers from improper use and disclosure, and (7) there is an adequate plan to destroy the identifiers at the earliest opportunity.[10]

The rules apply to individually identifiable health information. If the identifying information has been removed from a record to render the information de-identified, then it is no longer subject to the rules. In §164.514(a)-(c), the rules provide two alternative methods for determining when sufficient identifying information has been removed. First, it establishes a safe harbor if all of a list of 19 specified items (e.g., social security number, name, address) had been removed. Second, covered entities with sufficient expertise could remove or encrypt a different combination of information than the enumerated list, providing it also rendered the information unidentifiable.

However, a related issue directly affecting the IRB is exculpatory language within consent forms, defined as, "any language ... through which the subject is made to waive, or to appear to waive, any of the subject's legal rights, or releases, or appears to release, the investigator, the sponsor, the

institution, or its agents from liability."[11] The Food and Drug Administration (FDA) and the Office for Human Research Protection (OHRP) take broad view of what constitutes exculpatory language. Therefore, if there exists a suggestion that a study subject is surrendering any legal rights, for example, rights of privacy, the FDA and OHRP may interpret that language as exculpatory and, therefore, impermissible.

In addition, recently in Oklahoma, a lawsuit was filed against individual IRB members by a private claimant.[12] This complaint is believed to be the first against individual IRB members in the United States. As a result, IRB will have to be wary of private lawsuits in addition to increased governmental scrutiny.[13] Thus, given the potential liability and high risk, IRBs would be well-advised to review the current policies and procedures, making sure they are in compliance with all federal regulations.

The state of Oregon has gone one big step further and passed what some consider a very pro-privacy of its own called Genetic Privacy Act.[14] Included in the statute is a clause which establishes that each individual owns his or her own DNA, and, thus, is entitled to exercise autonomy over its use.[15,16] This provision has come under fire from various researchers, pharmaceutical companies, and biotechnology organizations which argue that it interferes with the ability to collect disease-associated data. In essence, it would require firms and/or researchers to obtain explicit authorization from individuals before using their DNA for commercial or research purposes. A similar concept has been proposed recently for the licensing and use of human cells and other human tissue by university labs to corporate research divisions.[17] However, the Oregon legislature is currently considering removal of the property clause.

In addition to rules or laws that regulate the disclosure of personal medical information, the United States Government is also considering enacting regulations that would govern the administration of genetic tests and appropriate treatment of the data collected from such testing. For example, in 1998, HHS established the Secretary's Advisory Committee on Genetic Testing (SACGT) to determine, among other things, whether additional oversight is necessary for genetic tests. Part of the rationale was that, unlike traditional *in vitro* tests that provide information on the current health status of a patient (e.g., whether they are infected by a particular microbe or have elevated cholesterol), genetic tests have predictive power.

That is to say, they can provide some indication of an individual's (and in some cases his or her progeny's) predisposition to a particular disease. SACGT concluded that, because of the predictive power of genetic tests and, thus, the greater harm their misuse or misinterpretation could cause individuals and their families, these tests should not be administered unless the individuals are fully informed of the risks and benefits, and a written informed consent has been obtained.[18]

Experimental or unapproved FDA genetic tests still in the research phase of development constitute another category that SAGCT believes requires additional oversight. SAGCT recommends that IRB review should be required of all research protocols involving such tests, regardless of the funding source. In addition, informed consent must be obtained from all subjects participating in such research.[18]

Thus, the landscape is filled with many potential legal landmines that could explode on technology licensing offices unaware of their presence. Before embarking down the path of establishing a data mining start-up or licensing strategy, technology transfer and licensing offices would be well-advised to become very familiar with applicable federal and state laws and regulations so as not to run afoul of them, for noncompliance could have civil penalties.

Some basic questions that should be addressed include the following. Does the proposal include the transfer of tissue or blood samples and medical information or just medical information? If it involves the transfer of human specimens, then individual informed consent may be unavoidable. If it only involves medical information, then how will it be used (e.g., research) and by whom? Furthermore, will the information being transferred fall under the HIPAA definition of individually identifiable health information? If not, then state laws may only apply. If it does fall under the HIPAA definition of individually identifiable health information, and if it is being sought for research purposes, then it might be advisable to seek a waiver from authorization from an IRB. However, if the records include genetic information or unapproved FDA test results (e.g., experimental test method results), then individual authorization may be required.

Although this process seems daunting from a legal standpoint, it is, nevertheless, being done. At least one new firm is in the business of collecting molecular and clinical information from various institutions (e.g., university

hospitals and nonprofit organizations) and marketing the materials and associated information to industry to advance its drug discovery research and development. One of the keys to the firm's success is its informed consent form.

For those interested in becoming more familiar with the applicable laws and regulations, we suggest that you consult the many excellent resources on the World Wide Web.[19] In addition, as part of the new HIPAA rules, each covered entity will be required to designate a privacy officer responsible for compliance with HIPAA. This person would be another excellent source of information. A very good organization to consult is the Privacy Officers Association (www.privacyassociation.org). It provides educational programs and information to its members and the public.

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