VOLUME 3, ISSUE 2

Intellectual Property and Higher Education: Challenges and Conflicts

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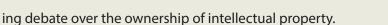
Intellectual property has become a highly coveted asset that can potentially reap a financial windfall for the owner who exploits its utility. Higher education has focused on the discovery of new knowledge, which can translate into intellectual property, but legislation, higher education policy, and/or contractual engagement may dictate ownership or opportunities for ownership of intellectual property by those involved in the discovery process. The dissemination of new knowledge acquired in the discovery of intellectual property may be limited for purposes of protection of commercial development. At the same time, higher education is becoming more involved in the oversight of technology transfer, oversight that includes seeking funding for academic research by private investors, licensing of intellectual property, and serving as a liaison for economic development for local communities. Because of the investment of time and resources in the development of intellectual property, a discovery may result in conflict over ownership, which may, in turn, lead to litigation. The complexity of the overall process of academic discovery moving into commercialization is fraught with challenges and potential conflict.

Keywords: university intellectual property, discovery, litigation, university intellectual property policy, Bayh-Dole Act, technology transfer departments

INTRODUCTION

Intellectual properties are products of the human intellect that are unique, new and innovative, have some value in the marketplace, and are the creation of a single person or a team. Intellectual property can be an idea, an invention, a patented work, an expression or literary creation, a copyrighted work, a trademark, an industrial process, a composition of matter, a medicinal formulation, a computer program, a presentation, or data of digital magnetic origin.¹ While it may seem that almost anything can be considered intellectual property and fall into one of the previous-ly mentioned categories, such is not the case. Consider a recent Supreme Court ruling regarding the discovery of the precise location and sequence of genes, mutations of which can dramatically increase the risk of breast and ovarian cancer.² Myriad Genetics, a molecular diagnostic company, obtained several patents from this discovery. Myriad then developed medical tests useful for determining a patient's cancer risk. However, the Supreme Court ruled that the patents obtain by Myriad were invalid because they were covered "products of nature." While a tremendous amount of intellectual effort was expended to determine the gene location and sequence, the Patent Act permits patents to be issued to "whoever invents or discovers any new and useful...composition of matter, but laws of nature, natural phenomena, and abstract ideas `are basic tools of scientific and technological work" that lie beyond the domain of patent protection.³

In recent years, intellectual property has become increasingly important to academic institutions throughout the United States. As research initiatives continue and expand, in part based on accreditation requirements, old and new issues arise regarding research discoveries. These issues include private sector sponsorship of university research, ownership of research discoveries, dissemination of new knowledge, and technology transfer policies. Also at issue today is whether universities will allow commercial forces to determine their educational missions and academic goals. Interaction and collaboration between university scientists and private firms have become the norm in many educational research facilities. Because of that connection, scientists today are well aware of the opportunity for financial incentives and security based on the commercial success of licensed products, which can result in a continu-



Because research can result in the creation of knowledge that may have commercial application, universities commonly have moved toward using a technology transfer department within the university to handle the complexities associated with the licensing of the commercial opportunities presented by university-created intellectual property. Nevertheless, questions arise as to whether these departments and institutions understand the multitude of issues surrounding intellectual property and whether these institutions are sufficiently protected by their current intellectual property policies. This article will explore the many concerns relating to intellectual property in the higher education environment.

PURPOSE OF HIGHER EDUCATION

Discovery and knowledge dissemination has always been a key component of the university mission. This dissemination of knowledge in the form of high quality academic publications, abstracts, conference proceedings, and invited presentations is a measure of success, both for the university and for the individual researcher. Knowledge generation and transfer is what we, as academics, do. It is our core business.

However, that core mission has been under challenge. While basic scientists would submit that discovery and knowledge dissemination, rather than profits, should be the focus, today, teaching and research institutions not only aim to serve the public interest with educational objectives, but also focus on the receipt of revenue through the exploitation of intellectual property created by university employees. The primary justification for adding commercial value as a component of the university mission relating to the dissemination of knowledge is that it promotes technological development for the benefit of society as a whole. Yet commercialization of research discoveries has, in many cases, discouraged the dissemination of knowledge in the public domain for the purpose of delaying the release of codified knowledge in scholarly publications in order to protect the novelty of patentable inventions. In such cases, it is profits, royalties, or licensing agreements that drive the university research machine, not research for the sake of research. Faculty, who in previous years may have been hired for their teaching skills or basic science research ability, may now be hired with a focus on expertise in a particular field for the specific purpose of developing intellectual property that can result in commercial application. Higher education no longer sees itself as being devoted merely to education and research. Today higher education also sets policy to assure commercial application of intellectual property.

This policy transformation of merging basic research and applied technology, particularly in the area of biotechnology, is common throughout the industrialized world and, in a more defined context, higher education. A linear model of the modern university with a focus on a profit-generating research mission may now be discovery, patenting, disclosure, licensing, assignment of patent rights, and knowledge dissemination in the form of education and publication. This mechanism for converting research into commercial application and subsequent knowledge for educational purposes is and will continue to be the model for research intensive institutions of higher education.

EVOLUTION OF RESEARCH

While research and the discovery of new knowledge has traditionally been encouraged by universities, federal and state legislation has also been a means to accomplish university based research and convert that research into economic gain. The view that universities can foster economic development through technology transfer dates back to the Morrill Act of 1862.⁴ The Morrill Act, signed by Abraham Lincoln, allocated public land in each state, based on the 1860 census, to establish what is commonly referred to today as land grant colleges. The grant amounted to 30,000 acres of land for every member of its congressional delegation. The land was then sold off to fund public colleges, with a particular focus on schools that specialized in agriculture, engineering, and science. The act ultimately funded 69 universities.⁵

In 1890, during the Industrial Revolution, another Morrill Act was passed that also increased the endowment and support to colleges for the agricultural and mechanical arts and extended the land grant provisions to sixteen southern states.⁶ The Morrill Acts were a major boost to higher education in America as they led to the establishment of extension services as a means of technology transfer and economic development activities.

Wars also have had a propensity to generate research. World War II played a key role in increasing the practice of encouraging university inventions. The government during this time did not have the resources to conduct all the scientific projects necessary to win the war. The need to use the best available technology and know-how created a rapid proliferation of government-sponsored research agreements.⁷ An example of this was the \$6,000-funded research team that would ultimately embark on the two billion dollar Manhattan Project, which was designed to research and produce an atomic bomb.⁸ Congress continued after World War II to fund university sponsored research. In 1950, Congress allocated \$15 million to establish the National Science Foundation (NSF) to support basic scientific research at universities and continues today to fund, through a variety of methods, research initiatives.⁹

BASIC VERSUS APPLIED RESEARCH

Basic research is driven by a scientist's curiosity or interest in a scientific question. The main motivation has been to expand human knowledge, not to create or invent something. Generally, there is no obvious commercial value to the discoveries that result from basic research. Applied research, however, is designed to solve practical problems of the modern world, rather than to acquire knowledge for knowledge's sake. This type of research commonly results in discoveries with commercial application and, as a result, possible patentable products.

The demand-side pull of patents may lead universities to favor research pathways that generate patentable results. The result may be to fundamentally skew university-provided infrastructure toward applied, readily commercialized, and profitable research at the expense of basic research that generates greater long-term spillovers.¹⁰ Academic patenting, fueled by profit motives, may critically alter university research agendas. The allure of patents and commercial interests for universities will in all likelihood increase. Contrary to this applied research commercialization aspect promoted by private industry, the most significant funder of university research—the federal government—has traditionally focused on basic rather than applied research. For example, the National Institutes of Health, which provides about thirty billion dollars per year for biomedical research, largely funds fundamental biological investigations rather than research with immediate commercial application.¹¹ Unfortunately, the future of such funding may be in question as government deficits mount and expenditures are limited to projects with possible application.

INTELLECTUAL PROPERTY: WHAT HAS VALUE?

Intellectual property is commonly deemed patentable inventions or discoveries, trademarks, or copyright items. These patents may be viewed as the crown jewel for the university, as they provide a vehicle for universities to project their unique norms and objectives into the marketplace and, at the same time, reap a financial benefit. Even though new knowledge may be considered intellectual property and may be patentable, not all intellectual property may have value to a university.

For instance, patenting of basic biomedical tools could potentially inhibit basic research; therefore, universities may conscientiously choose not to patent certain discoveries—such as DNA sequences that only serve as markers—which can be foundational research tools, and by so doing assure wide availability in the public domain.¹² Another method universities can use to assure widespread distribution and adoption of discoveries that are patented at university expense is the use of royalty-free nonexclusive licenses for academic research, allowing the use of such technology to be acquired at much lower fees than that of the commercial use application.¹³ In effect, there is a bifurcation of the discovery into a research use versus commercialization pool, creating an opportunity for affordable access for noncommercial research purposes.

Universities may also use their patents to push non-market objectives. For example, universities are leveraging their patents on essential medicines to enhance the availability of such products to underserved communities. Such is the case with AIDS medicines.¹⁴ One well-documented case involves Yale University, which patented Stavudine, a medicine used in antiretroviral combination therapy useful in treating HIV infections. Yale exclusively licensed the patent to Bristol-Myers-Squibb (BMS), which manufactured the medicine. With the urging of Medecins San Frontieres, Yale and BMS entered into an agreement whereby they would permit the sale of generics in South Africa; additionally, BMS agreed to substantially lower the price for stavudine throughout sub-Saharan Africa for governments and non-profit organizations, thus enhancing access to this critical therapeutic resource.¹⁵ Such an action can reflect the altruistic nature of the university community.



OWNERSHIP OF INTELLECTUAL PROPERTY AND LEGISLATION

Before 1980, the Federal Government's consistent position was that the results of any research and development funded with taxpayer's money should be in the public domain and freely available to the public. Absent protection to develop intellectual property created with some form of governmental funding, U.S. productivity began to fall and the Japanese economic engine began rising to competitively challenge domestic output.

To address these concerns, in 1980 Congress passed the Bayh-Dole Act, otherwise known as the Government Patent Policy Act.¹⁶ The impetus for Bayh-Dole was the belief that a wealth of basic, useful research developed in U.S. universities was languishing in those ivory towers. A frequently cited statistic in hearings on the Act was that, as of 1976, less than 5% of the 28,000 government-owned patents were licensed. This figure was attributed to private industry's reluctance to invest in commercializing federally funded research because they could not obtain exclusive rights to it. The Bayh-Dole Act provided a "bridge" over this valley by allowing universities to take title to inventions developed with federal funds and to grant exclusive licenses to entities willing to commercialize such technology.¹⁷

The outcome was also a change in the presumption of title to any invention made by small businesses and other nonprofit entities through the use of government funds from the government to the contractor-grantee. This act ended confusion and uncertainty over the ownership and commercialization of government sponsored research. Until that time, the ownership and commercialization of government sponsored research was governed by twenty-six separate federal agency regulations. The Act permitted organizations to retain title to inventions they created while working on a government sponsored program, apply for and receive patents when appropriate, and pursue options to commercialize their discoveries.¹⁸ The Act was expanded in 1983 by a presidential memorandum to cover any private party to a funding agreement.¹⁹This expansion permitted large, for-profit companies to also retain title to inventions developed with federal governmental funding in order to accelerate the commercialization of technology for the public's benefit.

Before the passage of Bayh-Dole legislation, universities, as a general matter, did not aggressively pursue intellectual property rights. Exceptions to this are evident as may be noted by reviewing actions of the Wisconsin Alumni Research Foundation, which was chartered in 1925.²⁰ The passage of the Bayh-Dole Act of 1980 ushered in a second era characterized by vastly increased university licensing, as well as concomitant rises in technology transfer offices, licensing revenues, and, most controversial, commercial influences on universities. Since the passage of the Bayh-Dole Act, universities and other public research organizations have been some of the most active patent producers in biotechnology, and patent licenses and options executed have increased steadily.²¹ Nevertheless, while universities still retain the right to taxpayer-funded inventions under Bayh-Dole, they do not exercise that right indiscriminately. In some cases, universities forebear upstream research tools so as to enhance their widespread availability, as was previously mentioned.²²

Because of the Bayh-Dole Act, research and development managers increasingly have approached research-producing universities to help industry meet the demand for growth and innovation. Seeing the potential for mutual economic benefit, university administrators embraced the joint venture concept.²³ Agreements created from these joint ventures provided universities with new operating funds and offered companies funding academic research exclusive rights to that research. Because of the need to protect the prized information resulting from this research, information that typically flowed freely from academic endeavors now flowed in only one direction: to the source of the funding—the company. This restriction in knowledge dissemination was often viewed as compromising an academic's ethical posture. Companies played hardball based on contribution to the research endeavor. Companies insisted that funding would only be available and continue in return for research secrecy and exclusive rights to the intellectual property produced. Because the money was such a tangible resource, both universities and their faculty have reluctantly relinquished ownership rights and, in so doing, their rights to an immediate open exchange of knowledge and information.

INTELLECTUAL PROPERTY AND UNIVERSITY POLICIES

The interest in the ownership by universities of intellectual property occasioned by the Bayh-Dole Act has precipitated rather intense efforts by many institutions to establish or refine policies defining the respective rights of all parties

to own, use, and otherwise profit from such intellectual property.²⁴ While it makes sense that universities would need such policies, a survey reported in 2002 indicated that the majority of universities had no intellectual property rights policies or policies.²⁵ However, the last few years have witnessed a dramatic change in that circumstance, as policies regarding ownership of intellectual property are now readily accessible on the websites of many, if not most, U.S. colleges and universities. Even regional universities, not traditionally considered to be research intensive institutions, are likewise implementing extensive policies dealing with these same issues.

While typical university intellectual property policies include a statement of purposes and objectives—such as encouraging creativity, fostering innovation, the sharing of ideas, and the protecting of academic freedom—the overriding reasons for such polices may really be to define who owns intellectual property and thereby provide, through careful guidance, for the future generation of revenue for the university. For example, Boston College's Policies and Procedures Manual expressly recognizes that "scholarly and research efforts often have social and commercial implications" and explains that its policy is designed to "define the conditions of ownership, legal protection, development and licensing of intellectual properties conceived or first reduced to practice by any Boston College employee or student." ²⁶ Harvard University has a similar approach, but further clarifies the importance of exploiting the possible financial windfall by stating in its policy that, "Although this policy recognizes that public benefit should be placed before financial gain, it is appropriate and often desirable for the University and inventors and authors to benefit financially from the use of a particular invention or creative work." ²⁷

Once creativity and money start to mix, there can be tension between those who believe that they are entitled to a vested right of ownership. Creators and inventors of intellectual property can easily rationalize that if they invented a product, they should own it. However, university policies typically alter this assumption. Polices must be drafted in such a way to define ownership rights so that administrators, faculty, staff, and students my peacefully co-exist. In general, university intellectual property policies cast a wide net in bringing a variety of works and inventions under the umbrella of the policy. Frankly, anytime intellectual property is created at the institution's direction, on its premises, with its resources, by its employees, students, or by grants awarded, there is a high likelihood that the policies will apply, specifying ownership rights and/or sharing of royalties or profits.

Polices, much like contracts, need to be clear and unambiguous, addressing common issues and providing for methods of conflict resolution. University legal counsel should closely supervise the drafting and editing of such documents even though such policies may be put forth by Intellectual Property Committees. Final approval by administration of such proposed policies should include close examination and may require several drafts exchanged between the committee and administration. In light of recent litigation, periodic review of these policies should take place in order to address concerns. All those involved as stakeholders should be made aware of policies and policy changes, and should be provided with in-services regarding current university policies, thus potentially addressing concerns that can arise over ownership issues. Some universities are known to provide these mandates to faculty on an annual basis, the purpose of which is to give notice to faculty members of the ongoing importance of the intellectual property policies.

In the event of a dispute over ownership of intellectual property, policies should be in place to provide express provisions for potentially controversial interpretations and determinations of ownership under the policy. Policies should clearly set forth procedures for resolution of disputes, which will hopefully avoid litigation. Such policies will detail the grievance process, methods of mediation, possible hearings, and even possible appeals, which may conclude with a decision by the university president.²⁸

OWNERSHIP OF KNOWLEDGE AND DISCOVERY

In recent years, universities have taken the approach with regard to intellectual property that all inventions, patentable products, or copyrightable materials are subject to university policy, which typically gives the university first claim to the right of ownership. While such policies may allow universities to claim ownership, these same policies often expressly acknowledge the possibility of the university waiving or releasing such right in favor of the inventor or author.²⁹ The university may do so if it believes that the discovery or invention is non-patentable, or that it does not warrant further evaluation as to patentability, or if a discovery or invention is returned to the university after negative evaluation by its patent evaluation agent(s). Universities may likewise simply ignore the creation of newly created in-

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tellectual property because of a lack of interest by the university in pursing ownership, even though such ownership is clearly permitted by university policy. A variety of reasons may exist for the university to ignore such intellectual property. For example, these creations may not generate interest for the university because the technology transfer department does not understand the significance of the discovery. In some cases, administrations may view certain types of intellectual property as not worth the effort to protect, or there may be a lack of interest among university officials in enforcing policies intended to benefit the university.

While policies regarding intellectual property may appear to clearly vest ownership in the university, a variety of situations may raise questions about that ownership. Not all situations neatly fit into the policies addressing intellectual property ownership. For example, one might ask who owns the intellectual property created by a faculty member who conducts research on a product, leaves and goes to another university or private organization, and then completes the research. If the research was conducted on personal time and used minimal university resources, who owns the intellectual property? What is "minimal university resources"? Who owns intellectual property, and to what degree, when a private sponsor who provided financial or other support withdraws from the project before the research is completed? Would partial ownership be applicable? While the university policy is the logical place to denote ownership based on unique situations, not all situations can be foreseen. Litigation has resulted when the clarity of ownership of intellectual property is uncertain and parties are disputing who owns what.

It is not uncommon for universities to address student creations of intellectual property in much the same way as faculty creations are handled. Typically the university view would be that, if the student was an employee performing work for hire or sponsored by commissioned research, or who had made significant use of the university resources, then the university reserves the right to claim ownership in the student's creation.³⁰ Students, especially at the undergraduate level, are becoming more involved in research projects. Today these students are acutely aware of the reward that may await a new discovery, considering the visibility of other young people who are finding financial success for their applied intellectual property products. Policies, once again, should be clearly drafted to address ownership of intellectual property by the university in relation to both graduate and undergraduate students. General university policies may include clauses indicating that, as a condition of enrollment, students will be subject to the policy regarding intellectual property and, simultaneously upon enrollment, grant the university a royalty-free license to use their works even if the circumstances under the policy do not lead to university ownership of the work.³¹

General university policies regarding intellectual property may yield to specific research policy handbooks when it comes to this topic involving students. For example, Stanford University details guidelines on relationships between students, including postdoctoral students and outside entities, in its Research Policy Handbook.³² While such policies may encourage research activities, these same policies can declare that both the university and the outside entity may retain ownership rights in any resulting intellectual property created by the student.³³

CONCERNS REGARDING PUBLICATION OF NEW KNOWLEDGE

While universities may encourage the creation of intellectual property, disseminating such knowledge may be tempered by the applicable commercial value of the knowledge and the need to protect it prior to publication. This is especially true when universities accept sponsored research grants from industry which demands restricted access to results.³⁴ Contract clauses in these private grants may specify delays or limitations in the publication of research results, with the natural outcome being a suppression of research results for the purpose of commercial gain.³⁵ Intellectual property created with private funding, for their purpose, to be used in application for the creation of a profitable product, will necessarily need to have restrictive access consistent with any other company trade secret. All this delay in openness makes perfect sense, considering that private enterprise is well known for protecting trade secrets. It is accepted business practice for a commercial enterprise to vigorously defend patentable property and trade secrets.

Competition for private and public funds has encouraged universities to accept sponsored research grants from industry that restrict access to results. Contract clauses specifying delays or limitations in the publication of research results and the possibility of the suppression of research results for commercial gain are and should be a grave concern. Higher educational institutions should find some conflict, possibly academic schizophrenia, with this thought as contrary to their primary purposes: the creation and dissemination of knowledge. Since the government is so involved in sponsoring research, the NIH recommends that universities allow corporate sponsors to prohibit the publication of new knowledge for no more than one or two months.³⁶ This is the typical time required to file a patent application. On a practical note, while an immediate news release might indicate the creation of new intellectual property, publication of such information in a peer reviewed journal detailing the find may be months away.

Since the passage of the Bayh-Dole Act, lengthier delays in knowledge dissemination are becoming standard. For example, in exchange for \$25 million to fund basic research in the Department of Plant and Microbial Biology, "Berkley granted Norvartis first right to negotiate licenses on roughly a third of the department's discoveries" and allowed Novartis to postpone publication for up to four months.³⁷ Such delays will probably become typical, versus the exception, as more power is exerted by private investment in research endeavors. This power can be noted in industry's contribution to academia of approximately two billion dollars per year.³⁸

UNIVERSITY LICENSING OF DISCOVERIES AND TECHNOLOGY TRANSFER

While higher education may be interested in capitalizing on intellectual property, the expense of attaching commercial value to knowledge is not cost-free. Initially significant funds will need to be allocated by the university to set up the infrastructure for capturing the commercial value of transferred knowledge. This begins by establishing a technology transfer office. This office may begin with a single individual sitting in the university's main research center, or the function could be carried out by engaging companies with multiple personnel with technology transfer expertise. In any event, success is not guaranteed, but costs are. Regional or smaller universities with limited funds and high aspirations will find themselves competing with large university operations for research faculty, private funding, government grants, and adequate research facilities, and may find themselves struggling for years to meet strategic goals with the capability of producing any results. These organizations must realize that there will be instances in which infrastructure costs may far outweigh the returns.

Patents are a key to the protection of intellectual property and generation of revenue. And while patents may be important to the university, the real measure of success may be viewed as the amount of patented technology that has been transferred to the private sector for further development into commercially viable products and processes that are useful to society.³⁹ However, different universities will have different philosophies regarding the extent to which they will pursue patent opportunities, and it is the technology transfer department that will be the go-to group for oversight and decision-making in this area. Many universities, such as the University of California and Columbia University, have been particularly aggressive in seeking and asserting patent protection.⁴⁰ Others, however, owing to their unique culture, such as Johns Hopkins University—a major recipient of research funds—have been reluctant to assert intellectual property rights on their discoveries.⁴¹

Revenue maximization continues to constitute the overriding focus of most university technology transfer activities. Today, universities operate technology-licensing offices to manage their patent portfolios as aggressively as any private enterprise would.⁴² Offices of "technology transfer" are becoming offices of "technology transfer and economic development."⁴³ There is now a growing trend toward universities pressuring their technology transfer specialists to become not only stewards of the universities' intellectual property assets, but also to serve as liaisons to the region's economic development. Trends in academic patenting indicate the importance of academic research to economic gain not only to the university but also to the region and state in which the university is located. There is increasing pressure on universities to forge stronger relations with local government economic development agencies, as well as the business community.⁴⁴

CONTRACTUAL AGREEMENTS REGARDING DISCOVERY

There appears to be a trend of "privatization" even of public universities, such that the real distinction between public and private universities may soon have little analytical value. More and more, university faculty, regardless of whether working for a public or private university, look to what corporations want researched because corporations that once gave unrestricted money to colleges to cultivate good will now mainly want projects that have direct commercial payoffs.⁴⁵ Furthermore, corporations typically ask, and rightfully so, for the first, and possibly exclusive rights to intellectual property resulting from research.

The practical benefit associated with the drive to realize the commercial value of knowledge is that it provides a re-

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turn on investment by allowing governments and funding agencies the opportunity to reduce their own monetary contribution to research. This concept allows universities to, by way of revenue-generating creations, self-fund their future and reduce the funding needed from state governments, which has in many ways been reduced over the last few years. Universities may do so either by direct ownership or by way of obtaining a share of royalties from the private organization thereby maintaining to some degree ownership in the intellectual property.

Some have suggested that the cozy relationship with industry is disturbing, as universities should be pursing research for the sake of developing a body of knowledge in various disciplines rather than collaborating with private industry. Nonetheless, these relationships continue to develop. In the previously mentioned deal struck between Novartis and the University of California, Berkeley, Novartis, the Swiss biotechnology and agrochemical firm, was to provide \$25 million per year along with proprietary technology and DNA databases to UC Berkeley's Department of Plant and Microbial Biology in the College of Natural Resources. What did Novartis receive in return? The benefit for Novartis was the option to receive first right to negotiate for roughly thirty to forty percent of the discoveries made in the department.⁴⁶ This arrangement, while benefitting a private company, also benefitted the university and had the potential to benefit, in some way, society at large. While some might see the agreement as offensive, others could justify the contract as win-win-win.

ECONOMIC AND FINANCIAL IMPACT OF DISCOVERY

Today, universities operate in an economic climate that requires both capital and knowledge, taking advantage of government technology initiatives (namely the Bayh-Dole Act), and serving as a catalyst for the creation of a large number of new, incubated companies.⁴⁷ There is great opportunity in creating a system that can capitalize on intellectual property transfer. In 1998 alone, colleges amassed more than \$576 million in royalties from inventions licensed to industry and were awarded more than 2,681 patents. The institutions surveyed reported 279 start-up companies based on inventions by their faculty or graduate students.⁴⁸ Fast forward to 2004 and one finds that, in that year alone, approximately 154 U.S. universities reaped over \$1 billion in net patent licensing income, executed 3,928 new licenses, and were issued over 3,800 patents, largely as a result of some type of university-industry technology transfer initiatives.⁴⁹ Based on data from the Association of University Technology Managers, hundreds of start-up companies are formed annually on the basis of licensed academic inventions.⁵⁰

In the 1980s, after Congress passed the Bayh-Dole Act, the small business incubator model began to be used for university and federally funded lab technology commercialization.⁵¹ Generally, incubators receive financial backing from a number of resources. Overall, however, in the 1990s, the largest contributors were local and state governments, foundations, academic institutions, corporations, financial institutions, and economic development agencies (EDA).⁵² The majority of incubators are owned and operated by economic development agencies, yet universities are known to sponsor technology incubators and are often willing to take equity as partial compensation for a license agreement since start-up companies are typically cash poor.⁵³

Likewise, there is tremendous outside pressure on universities to forge stronger relations with local government economic development agencies and the business community.⁵⁴ Local governments may see the university research community as a source of potential revenue in the form of startup companies and entrepreneurial activity. Universities are a rich source of science and technology that can support local government and business development, as well as economic growth. In some cases, local governments are willing to support the development of these technologically rich environments. In 1996, the Association of University Technology Managers (AUTM) estimated that a survey of licensing activities of academic institutions, nonprofit organizations, and patent management firms add more than \$24.8 billion and 212,500 jobs to the U.S. national economy each year.⁵⁵ Another study estimates that technology transfer programs put \$434 million into local economies annually.⁵⁶ Therefore universities can have a great seedbed effect on their local economic environment.

Technology transfer specialists need proper training in order to facilitate communication and build coalitions between the relevant local economic planning entities in the public and private sector.⁵⁷ University technology transfer offices and entrepreneurship programs personnel and the inventors with whom they work would no doubt attest that there is often a substantial amount of red tape involved in the process of seizing opportunities to commercialize university-generated inventions, but it can work with commitment and planning.⁵⁸ The development of small businesses and entrepreneurial projects is an important component of economic growth, and incubators can provide the forum for these collaborations. These incubators may position themselves directly in the development path between the laboratory or university and the market.⁵⁹ Incubators are not only important for job creation, but also for wealth creation, industrial regeneration, and technology transfer.

FACULTY REWARDS

Although it is true that most universities are prepared to let their professors fully enjoy the insignificant rewards of publishing an article, they continue to formulate policies that assert their joint or full ownership over property that is created with the use of university materials or facilities by faculty.⁶⁰ But even with ownership assured by the university under polices, many universities provide some sort of split-royalty provision, thereby allowing the faculty member to reap some financial reward from their efforts. Other financial rewards may flow back into the department of the faculty member so that funding will be available for future research needs. The pot of gold reaped from intellectual property on the university campus is seldom reserved to one party, but rather is distribute to multiple parties. As a result, accounting measures need to be put in place to assure proper dispersal of receipts of royalties received by the institution.

LITIGATION ASSOCIATED WITH INTELLECTUAL PROPERTY

The commercialization of knowledge brings together a unique collection of collaborators: university administrators, researchers, and industry. Each of these groups is likely to bring quite different interests, agendas, and experience to the bargaining table. Administrators certainly are considering cost recovery by way of licensing fees and ongoing contractual benefits. Researchers understand the technology and science involved. Industry, on the other hand, is concerned about commercial production, marketing, and long-term benefits of product development. Nevertheless, all of these groups bring to the table the concern of determining ownership and value of the discovered item. Who owns it? What is it worth? How will the proceeds be shared, if at all? When will fees be paid? Will there be restrictions on product distribution or production?

What all of this should tell us is that these parties may have different agendas, but little guidance in creating a working contract. Yet details in such documents are critical. Intellectual property attorneys are necessary to craft working contracts that provide details for clarity between the parties. They should be engaged early and consulted often in order to address concerns and prevent, if possible, litigation regarding intellectual property.

However, even with a comprehensive contract and/or policy, litigation may ensue. For example, Interactive Return Service(IRS), a corporation sponsored research at Virginia Polytechnic Institute (also known as Virginia Tech) and agreed to reimburse the university for the costs incurred to conduct research and development. The corporation stopped making payments early, yet, six months later, agreed to enter into an industry project agreement with an intellectual property company that was to address funding for the research and intellectual property rights. Another six months passed, and the university ceased working on the project, assigning its rights to another intellectual property rompany, and then that company licensed those rights to a third party. IRS then filed a breach of contract action against Virginia Tech. The court ruled that the first company, IRS, may still have property rights, even though it failed to make appropriate payments, as the university waived its requirement for prompt payment because of its past history of working on the project without requirement of prompt payment. In this case, Virginia Tech kept the agreement alive by not requiring prompt payment. This and the fact that Virginia Tech sold the license to a third party did permit the possibility of damages to the originally contracting party, which ultimately resulted in an award of \$110,000 to IRS.⁶¹

In the case of *University of Pittsburgh v. Townsend*, the university alleged that the defendants Townsend and Nutt subverted and misappropriated the university's rights and interests in valuable medical scanning technology, namely a combined PET/CT scanner that was developed collaboratively at its campus over the course of several years.⁶² The university also alleged that the defendants' wrongful actions included breaches of, and interference with, the University of Pittsburg's contractual rights to joint ownership in the technology, as well as tortuous misrepresentations and misappropriation. The university also alleged ownership in certain patents.



Dr. Townsend, when hired by the university, disclosed the existence of his agreement to the university through conflict of interest forms. While federal research grants are applied for by professors, any funds awarded are paid directly to the applicable university. Though a grant from the NIH was utilized for certain research performed by Townsend, Townsend testified that there was no NIH funding for the clinical validation of the PET/CT scanner, and that, in fact, NIH had specifically declined to fund the clinical portion of the process. However, the NIH Final Report stated that the original grant proposal did include funding from a preliminary clinical evaluation of the scanner.

The key to this case is that the university should have been able to see that Townsend had assigned his rights to the invention to another company, and not to the university, as the university claimed he was required to do. The University of Pittsburg claimed that Townsend committed fraud in concealing his assignment and, because of that action, the statute of limitations on the action should be tolled until the fraud was identified. The court held, however, that, because of the prior disclosure by Townsend, the university's mistake, misunderstanding, or lack of knowledge in regard to Townsend was simply not sufficient to toll the statute of limitations. The prior actual notice of Townsend's conflict of interest arising from his assignment of his ownership could easily have been discovered by reasonable due diligence of the university.

In yet another case a dispute arose over an invention in the field of mass spectrometry that Dr. John Fenn developed at Yale University.⁶³ Fenn was an expert in the field of mass spectrometry, eventually winning the Nobel Prize for the mass spectrometry invention which was the subject of the dispute. Even before Fenn joined Yale in 1967, Yale had policies that provided that patentable inventions resulting from a faculty member's research conducted at Yale belong to Yale and the faculty member, unless Yale expressly released its interest in such inventions. Fenn would have been aware of such policies, as evidence indicated that he had served on panels at Yale that reviewed the institution's policy on intellectual property.

The threshold question in this case was whether university intellectual property policies are generally enforceable. The federal district court in Connecticut answered in the affirmative, stating that, "University patent polices such as Yale's have long been recognized as a valid and enforceable part of the contract of employment."⁶⁴ In general, court opinions have favored university enforcement of such policies, despite some arguable grounds to at least question that outcome.

The course of this case resulted in Fenn bringing an action against the university, alleging conversion, theft, tortuous interference with a business relationship, and violations of the Connecticut Unfair Trade Practices Act (CUTPA) after Yale entered into its own licensing agreement with a private company to market the invention. The action concerned a patent that was issued to the professor while he was working for the university. The university asserted counterclaims against the professor, seeking an accounting and assignment of the patent, as well as damages for breach of contract and fiduciary duty, fraud, negligent misrepresentation, conversion, theft, and CUTPA violations.

The court found that the professor violated the university's patent policy and committed a material breach of the policy. The court also found that the professor had engaged in fraudulent misrepresentation and fraudulent nondisclosure. Fenn had stated to Yale that he did not believe the invention had the potential for much commercial value because any patent issued would be a "use" patent, as opposed to an "apparatus" patent, and, as such, it would be difficult to protect against infringement. Fenn did not disclose that Pfizer Corporation, colleagues at the Yale Medical School, and others had previously expressed a strong interest in the commercial viability of the invention. Fenn also did not disclose his own view, and the view of others, that the invention was in fact "revolutionary" or "important" and that it would likely have substantial commercial value. Yale, therefore, had not filed a patent application before the statutory deadline, relying on Fenn's representations about the importance of the invention. Nevertheless Fenn, in his own name, and within the statutory time frame, filed a patent application that was financed by a company that had exploited some of Fenn's prior inventions and who subsequently received licensing of the patent from Fenn. The court ruled against Fenn, awarding Yale \$545,000 in royalties and \$500,000 in legal fees.

CONCLUSION

Intellectual property created at the university level has resulted in challenges and conflicts. These challenges and conflicts revolve around ownership, disclosure of new knowledge, and relationships with private business entities.

Academic administrators, technology transfer departments, faculty, students, private investors, local governments, and attorneys all have become important players in determining how intellectual property can and will be used. Additional challenges and conflicts will arise as more universities expand their interest in intellectual property and as this area of law matures.

NOTES

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