

Overview of Common Intellectual Property Issues

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Abstract

The landscape has changed. Global competition, shrinking government research dollars and corporate strategy on selecting university partners have had a significant impact on the way colleges and universities interact/partner with industry. And an ever pressing issue in these collaborations is Intellectual Property.

This paper will address the main issues affecting academic/industry collaboration in regards to Intellectual Property. Concepts such as the Work for hire doctrine, copyright and patents will all be addressed as they impact the relationship. Furthermore, the changes brought about by the America Invents Act will be examined in regards to the impact on faculty research as well as corporate partnerships.

In addition, the paper will examine fundamental tensions in the academic/industry partnership. For example, academic endeavors seeking to create public knowledge are clearly at odds with industry desire to own and commercialize IP. Issues such as ‘open source code’ present unique challenges to academic/industry collaborations.

However, looking to the future, industry will play a very important role in academic research. For many faculty and university administrators, the ability to cement relationships with key industry sponsors will be necessary for advancement/competitiveness of their university in the years to come. To understand the IP issues from both sides may help foster a better appreciation for what each side brings to the table and, hopefully, a foundation for a better partnership.

Introduction

Intellectual property issues are one of the most significant issues facing productive university/industry partnerships. Addressing these issues at the outset of the relationship, and understanding not only the cultural issues but also the success metrics of each side, is key to advancing partnerships and resolving intellectual property matters.

The Landscape- Past, Present and Future

Historically, government has been the leading supporter of university research efforts. The National Science Foundation (NSF), National Institutes of Health (NIH), Defense Advanced Research Project Agency (DARPA), etc. are typically involved in sponsored research. In fact, the government provides the bulk of funding for the basic research (research for sake of

knowledge) which universities perform.ⁱ Government funds research for knowledge, not profit. In exchange, government typically receives a license to use the product of the research but the university is free to commercialize the research and license it to industry. Industry though, is now also looking to Universities for research. “As companies decrease the size and scope of their internal research laboratories, companies are increasingly turning to universities for basic research. Federal and state governments are developing funding programs that emphasize collaboration between universities and companies that will enhance translational research and support economic development.”ⁱⁱ

The 1980 passage of the Bayh-Dole Actⁱⁱⁱ accelerated industry-university partnership. Since its passage, 5,171 new companies have been formed that were based on the licensing of an invention from an academic institution and, from 1998 to 2005, 3,641 new products were developed and commercialized from academic technology transfer.^{iv} Bayh-Dole specifically allows universities to retain title to inventions developed with federal funding and encourages university-industry collaboration to promote commercialization of inventions.^v Setting the stage for future collaboration and innovation, Bayh-Dole’s encouragement of university-industry partnerships set a pathway to getting the innovation from the laboratories of the research universities to the corporate sector impacting products, jobs and American competitiveness. With government funding shrinking and industry needing new innovations to succeed, or gain a competitive edge, it seems like as perfect solution. But, Universities and industry need to address fundamental tensions for such a partnership to truly be successful.

Cultural issues in the University-Industry partnership

Universities and industry have very different missions. A university’s mission is to spread knowledge, innovate and seek knowledge, as well as educate the future workforce for industry. Fundamental to this mission is publication, dissemination of information and open communication. Conversely, industry’s mission is to make money, satisfy shareholders if publicly traded, create jobs and keep out in front of competition for success. Fundamental to this mission is the protection of trade secrets and confidential company data, communications that are private and confidential, and keeping a competitive advantage by protecting key technology and information. Therein lays the fundamental tension and intellectual property at the heart of university-industry collaborations/partnership, is often the most contentious issue.

Intellectual Property (IP) has value to both universities and industry. But what exactly is IP? Intellectual property refers to rights that attach to intangible creations. In university-industry partnerships, the main IP issues generally involve patents and copyrights, with trademarks to lesser extent. IP, in general, refers to a collection of rights held by not only inventors, but also authors, artists and musicians. IP rights are intangible but still a very important asset. For university faculty and researchers, patents on inventions and copyrights on papers, articles or software are most impactful. However, university administration positions on IP vary greatly.

The variety of university positions on IP covers the entire spectrum. On one end is WARF (Wisconsin Alumni Research Foundation). It is the technology transfer partner of the University of Wisconsin Madison with a very sophisticated system. WARF has earned more than \$800 million in patent royalty revenues, paid more than \$170 million to faculty and staff inventors and returned more than \$1.25 billion to the university while also building an endowment that is now worth some \$2 billion.^{vi} On the other end of the spectrum is Pennsylvania State University who

recently- effective December 16, 2011- declared “intellectual property that results from industry-sponsored research no longer is mandated to be owned by the University”.^{vii} This is not to say that Penn State finds no value in IP. The University carefully evaluated the impact of their IP policy on their corporate funded research and determined a path with the objective to “spur growth in corporately funded research with more flexible intellectual property policies.”^{viii} Hank Foley, Vice President of Research for Penn State University stated "In short we are doing it because we consider the net present value of the interactions and relationships that our faculty and students have with industrial professionals to be very important and therefore greater than the apparent future value of the proceeds from such intellectual property...and education is our core business."^{ix}

Education is the business of universities. But, in order to fulfill the mission, funds are needed. And in the present day climate of dwindling government research dollars, large state government cuts in education funding, rising costs of materials and the constant need to increase tuition; funds generated by IP royalties can be put to good use. Each university has its own financial situation and therefore will adapt an approach to IP rights in industry sponsored collaborations that best benefits its purpose. But all universities looking to partner with industry face common challenges such as the ‘work for hire’ doctrine, the “we pay for it we own it” position, global competition and the new changes brought about by the America Invents Act.

First, the doctrine of “Work for Hire” is a legal concept defined by the copyright law.^x A “work for hire” is defined as “a work prepared by an employee within the scope of his or her employment “ or one of the following: a work specially ordered or commissioned for use, a contribution to a collective work, a part of a motion picture or other audiovisual work, a translation, a supplementary work (work prepared for publication), a compilation, an instructional text, a test, answer material for a test, or an atlas, “if the parties expressly agree in a written instrument signed by them that the work shall be considered a work made for hire.”^{xi} Often in agreements with industry, the contract contains language classifying the work as “work for hire”. This is a concept unique to copyright law, not patent law. Inventors of a patent must be listed in accordance with patent law.^{xii} However, for creative works, most often software related research, the work for hire could apply. For universities, works for hire pose unique issues especially with regard to our not for profit status. But companies are used to dealing with other companies and many standard agreements have ‘work for hire’ language in them. This has evolved as a standard in industry relationships because of expensive IP lessons such as in the following example:

The president of a small medical records software company believes he lost at least two million in business for lack of simple IP protection. He hired a software developer to develop a key product, but the contract failed to address the “work made for hire” doctrine.... This unfortunate scenario came as a shock to the president of the medical records company, which paid over \$600,000 to develop the software. The unscrupulous developer who owned the copyright turned around and sold the software to several of the medical records company’s competitors for only \$50,000. If the medical records company had received the copyright via some simple language in the contract, then the software would have been owned exclusively by the company, instead of being offered at a substantial discount to its competitors.^{xiii}

In dealing with universities, companies are very concerned that development they pay for may be licensed to a competitor. Understanding this concern is vital to the success of the university-industry relationship. Though universities typically do not do “work for hire”, language in the contract can be crafted to address industry concerns at the outset. Universities often work with a number of companies, many competitors. Therefore, addressing the IP and publication issues up front helps set the stage for productive collaborations.

Second, a common industry position is “we own what we pay for”. For industry sponsoring research, a commonly held position is that all IP generated from funded research should belong to the company because they ‘paid for it’. However, in order for the research to be done in university labs, within university buildings, with university supplies, assisted by university undergraduate or graduate students, government and university funds are clearly used in the infrastructure. There is considerable investment on the part of the university to perpetuate the research, not just funds for a specific sponsored project. Helping industry partners understand the vast investment universities have made in their research enterprises can also assist in laying the foundation for better collaboration.

Third, consider global competition. Many large companies today are global in their reach. They operate in several countries on different continents. They draw their workforce from leading institutions around the globe. And there is competition among universities for research partnerships with these global companies. A report by the Council of Chemical Research states: Mr. Richard Lemuth, General Counsel for Shell Global Solutions, and several other company representatives, agreed that sponsoring university research in the U.S. presented challenges that do not exist when contracting with universities in other countries. Agreements were considered more complex and often involved protracted negotiations when establishing partnerships with U.S. universities. Research universities in other countries are seizing this opportunity and readily working with global industries to secure research funding.^{xiv} A large factor in this position was university policy on intellectual property. On the industry side, many large US-based companies are so frustrated with the US university stance that they are now preferentially working with elite foreign universities, which offer more favorable IP terms.^{xv} Companies may be increasing their collaborations with foreign universities based on more favorable IP terms and reducing their collaborations with U.S. universities that have difficult agreement processes.^{xvi} Understanding that global companies are searching for university partners around the globe, American universities need to understand IP policies with the bigger picture in mind in order to craft successful partnerships.

Finally, the America Invents Act (AIA)^{xvii} was signed into law September 16, 2011 and is the biggest change to patent law in almost 60 years. One of the most significant changes in the law goes into effect March 16, 2013. This changes our current system from a First to Invent system to a First to File system. Under the old law, inventors who could show he/she was the first to invent via inventor notebooks etc. could establish the right to patent an invention. Under the new law, the first to file the patent owns the invention. Though this does bring the United States in line with the rest of the world, some interesting issues arise. For university/industry partnerships, publication is at the center. Companies are very concerned about a publication (whether in a journal, student report or poster session) that would prevent a company from obtaining a patent. Universities should be aware of this heightened sensitivity and work to be a good partner in protecting IP rights prior to publication. Often, providing an industry partner the opportunity to

review an intended paper or presentation prior to publication will work to remove concern. In addition, the AIA also broadens the definition of “prior art” which may have a negative impact on the ‘one year grace period’ typically relied on by faculty inventors.

To promote a healthy relationship, a “middle-ground” approach may serve to further partnerships. Universities moving away from a mandate of owning all IP gives room for more flexible negotiation, especially for universities with smaller research programs. Universities invest hundreds of thousands of dollars in their research enterprises. Would it be more prudent to expand corporate partnerships and take a different approach on IP? Perhaps limited IP? For example, Millennium Pharmaceuticals has been creative in licensing gene IP to pharmaceutical firms for specific applications, while retaining the rights for all other applications.^{xviii}

A similar position may also work for universities. Understanding the issues industry partners face may help universities revise their publication process and create more formal (explicit) collaboration agreements detailing both parties’ understanding on IP rights and publication. A helpful analogy is, as fences make good neighbors, detailed contracts make good partners. After all, universities do not compete with industry or generally bring products to market, so with more flexible room for negotiation, many options are possible for win/win solutions. But this will require open dialogue about what both parties ‘bring to the table’ and a recognition of investments both past and future.

Issues with Open source code and Open Innovation models

There has been a movement over the past several years promoting open source software. By definition the software is “open” and the code is revealed. It is meant to be used freely by others to build upon and innovate. Developers of open source software do not claim IP protections. This presents an interesting issue for universities who develop on open source platforms and for companies who partner with universities seeking innovations to open source code.

Going back to the cultural difference in academia versus industry, open source fits well in the sharing of information but not so well in the proprietary culture. Does open source mean there are no IP issues? The answer is no. Copyright still plays a major role in open source software. For universities building upon open source as part of company sponsored research, the IP issues center around licensing. Open source code software is generally used under a license agreement. Just because it is open source it does not mean it is given away without any requirements. The most common license for open source is a GPL – General Public License. GPL’s typically require the source code be made available to users. If a company has engaged a university to develop software and it is based on open source GPL, the code to any improvements or innovations must generally also be made publically available per the GPL license.^{xix} There are other license arrangements for open source software that do not have the same requirements as a GPL. For companies seeking to create proprietary software applications, a license that allows protection of improvements or innovations to the software will be much more appealing. Understanding the licensing requirements is important to the partnership.

There is also another “open” movement to be aware of. Several global companies are leading the way with “open innovation.” Open innovation refers to a concept promoted by University of California Berkley professor Dr. Henry Chesbrough. “Open innovation is the use of purposive inflows and outflows of knowledge to accelerate internal innovation, and expand the markets for

external use of innovation, respectively. [This paradigm] assumes that firms can and should use external ideas as well as internal ideas, and internal and external paths to market, as they look to advance their technology.”^{xx} Open innovation models encourage companies to look beyond their internal resources and partner with others to develop new technologies. Philips is a leading global company that has embraced the open innovation model. On its website it claims:

Philips has adopted an Open Innovation strategy which leverages the joint innovative power of partnering companies and researchers to bring more innovations to the market effectively and faster.^{xxi}

Philips has also stated “this (innovation research) is often best carried out through partnerships. The days of innovating in isolation are over. No one company can be expected to know all the answers. That's why we regularly work together with a wide network of institutes, companies, universities and hospitals to jointly develop meaningful new breakthroughs.”^{xxii} Other companies, such as Intel, have embraced the Open Innovation model by funding researchers at universities without specifying the goal or area of the research precisely but require royalty-free licenses to any university patents emerging from the research that it has funded.^{xxiii}

Industry leaders are moving in a direction of more collaboration with external researchers to innovate and develop new products. The stars are aligning for increased industry sponsored research at universities if we are able to effectively handle the IP issues that arise.

Licensing in the University/Corporate interface

In 2011, there were 4,899 licenses signed and 591 new products commercialized in the United States, according to the Association of University Technology Manager's annual report.^{xxiv} There is a lot of interaction going on between industry and universities. As previously discussed, there are issues to overcome and a tension between the different cultures. Companies are looking to complement their business development portfolio, fill a pipeline gap, create a new enterprise opportunity, or provide joint research collaborations that could generate new intellectual property.

University principal investigators (PI) have their grants and teaching obligations as their primary responsibility. Now is a good time, however, for companies to enter universities and offer funding for company research protocols as federal grant funding has been drying up. A smaller and smaller percentage of grant proposals are being funded, and the prospect for increases in funding in the near future are dim, to say the least.

The technology transfer office (TLO) is motivated to move out as many technologies as possible before patent expenses become exorbitant. These offices, especially at public institutions, are under tremendous pressure to contain their patent expenses, while making sure they protect the best ideas. Most technologies from universities are at a very early stage, so it is difficult to “pick the winners.” The TLO does not want to walk away from any potential licensee, yet they do not want to give away technology either.

As an industry partner seeking to license a technology from an institution, there are some key items to be aware of and tips to help you prepare for that negotiation which will help increase your chances for a successful, time efficient transaction. First, it is important to understand the players involved. There is the TLO, the PI(s), and the company that are all part of the

transaction. The PI technically doesn't have an ability to influence the license transaction, as that person has assigned their rights to the IP over to the Institution. However, it is important to make sure the PI is engaged and happy with the transactions, especially if that person is needed to help with the transition from the institution to the company. The TLO is typically responsible for all of the negotiations of the license, but a licensee would be well advised to understand who in the office ultimately approves the terms and who will handle the legal document. Second, the institutional intellectual property policy is typically listed on the university's web site, and a licensee should review that prior to negotiations so they can understand the policy of the institution. It will give a feel for what the institution needs to comply with when negotiating. The licensee can also find out how the institution shares any revenues that may result from the license. Third, the cultural differences between industry and academia play a role in positioning for negotiation. It will be helpful to do due diligence on the TLO person you will be negotiating with because though some have extensive business backgrounds, others have none. Fourth, part of the negotiation may involve a consulting role for the PI if the PI is needed after the license is signed. The licensee should understand (from the IP Policy) how much time the PI is allowed to spend consulting. It is typically 20% of their time. This is especially important if the license is going to a startup company, where the PI time may have pressure to spend more than the allotted time. It also would be good to manage the PI expectations as the commercialization moves beyond their skill set. The licensee will have to instill confidence that the company has the development expertise to take over from the basic research.

Terms of the Licensing Deal

Terms in licenses will vary widely based on the stage of development. Obviously, if a technology has been heavily invested in through grants or other internal funding, and a product is ready to go to market, then the TLO will expect higher compensation than if it was much further back in the commercialization pathway. Often the TLO and PI may not appreciate what the commercialization steps are, especially if the technology needs to move from small, bench production to full scale commercialization.

Terms for startup companies will be very different than a straight license to a larger company. If it is a startup, the licensee should consider finding out about any other startups the institution has done work with and check with those companies for any suggestions in approaching the TLO. They may be constrained due to confidentiality in providing any specific terms, but they may be helpful in knowing how to approach the office. Typically the TLO will not expect any upfront payments for a startup, as they would rather see the cash go into the development of the technology. But they often will expect equity in return. This usually comes with some level of anti-dilution, which generally can be negotiated.

One of the most important terms in the license for the TLO will be due diligence. Their goal is generally to get the technology on the market as quickly as possible, and ideally, being produced in their local economic region, not only returning royalties, but creating more jobs. It is reasonable for the company to develop a business plan and some terms are tied to hitting milestones in that plan. The TLO should be willing to renegotiate if milestones are missed for legitimate reasons, but they will want diligence to be built in.

Another important term will be for the PI to have the ability to publish. The PIs at most institutions are judged, and rewarded, for scholarly publications. It is reasonable for the

company to ask to review any publication, usually 30-60 days prior to public release, and the company can request that any patentable material either be removed, or protected prior to the publication.

Indemnification is also often a sticking point in the negotiations. The institution won't allow the TLO to risk any "brick and mortar." This generally comes from the institution and their general counsel. The technology and IP will come "as is" without warranty. Companies sometimes want the TLO to guarantee that the patent doesn't infringe any other IP. The TLO won't be able to provide this sort of warranty.

It should be understood that, as a tax exempt, the institution will need to behave differently than a for profit company. For example, the institution can accept funding for research as part of the license, but the institution needs to control the research in order to protect its not for profit status. In other words, they can't provide "work for hire." Related to this, the license will often include a clause that allows the PI to continue to do research with the IP for internal, noncommercial purposes. This is often very important for the PI to continue their area of expertise. The company can request rights to improvements in the license. Usually the license will include the original IP, and any continuations, continuations in part, and divisionals.

Improvements can also be a sticking point in a license negotiation, depending upon how broadly the technology can be used. It is easy for a university to include improvements where the technology is narrowly defined in a certain field of use. However, there are times when there may be a broad platform technology that can be used for a variety of markets, and the company is only interested in or capable of reaching a limited number of these markets. Improvements can then be limited to just those fields of use, leaving the Institution free to pursue other licensees. This is further complicated if the technology is a potential solution for a variety of medical indications. A company may not want to allow the university to go into other indications as it may be investing millions of dollars going through a regulatory pathway, and the technology may not work well in a different indication and taint the licensee's ability to gain regulatory approval in their chosen indication.

However, a reason to include improvements would be to provide an incentive for both parties to continue to collaborate in the field and come up with a superior product than the one originally conceived. This could be a win-win for both parties. But, a company may object if they feel they have already paid for the intellectual property and this option forces them to pay again. It should be pointed out that they already have the rights to the existing intellectual property and the improvements would be in regard to new intellectual property as defined by patent law (as opposed to continuations, divisional, etc.), or new processes or methods that are not covered by claims that allow that intellectual property to be enabled.

One essential element that the university will want to guarantee when granting any improvement rights is that, in doing so, it does not put any limits on the university investigator from continuing to work freely in his/her field. In addition, if there was federal funding involved in the invention the licensee will need to understand that the government will retain certain rights to that invention.

Each licensing case will be different in how Improvements and follow on inventions are handled. The University will need to be sensitive to how the licensee can best create value from the

intellectual property, while the company should be recognizing and rewarding things that are beyond the scope of the original license.

Post License

Hopefully the negotiation has gone smoothly and quickly. The honeymoon period is wonderful, but now comes the hard work of converting this great research idea into a fully developed, successful product. The license will typically include some reporting of progress. The licensee would be well advised to stay in touch proactively with the TLO and provide progress reports, even if the news isn't good. Keeping an open dialog, without surprises, will make it much easier to go back and request amendments if the business plan has had to shift.

Conclusion

University-Industry partnerships are important to both parties. There is mutual benefit if win/win solutions can be crafted. Understanding the cultural differences and recognizing what is most important to each party is key to a successful negotiation. Central to any collaboration will be intellectual property rights. But those rights are not 'one size fits all'. Agreements that acknowledge the value each party holds and allows each party to derive the benefits they seek most are effective not only for the collaboration at hand, but also in forming a long term partnership.

Industry and academia are symbiotic: Universities have researchers undertaking new fundamental research that can give rise to new products and innovation and industry needs this research to compete and grow; when industry grows it needs well educated workers which universities provide. Each needs the other and both impact the other's mission.

Collaborations between industry and universities are key to America's future success. Looking to the future, industry will play an even larger role in university research efforts but competition for such partnerships will increase. To build successful industry alliances, universities should carefully evaluate their IP policy, employ contracts that are clear and set appropriate expectations, and focus on the value of the relationship as a whole as opposed to just a funding source for a one time project.

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