

PROTECTING UNIVERSITY PATENT RIGHTS
FOLLOWING STANFORD V. ROCHE,
FILMTEC CORP. V. ALLIED-SIGNAL, AND PATENT REFORM

by
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Abstract

The Bayh-Dole Act (“the Act”) was passed in 1980, permitting U.S. small businesses and nonprofit organizations (including universities) to elect retention of title to inventions created in federally-funded research. Since then, the Act has been the prevailing authority over university ownership of research patents.

In recent years, court decisions and patent reform laws have directly undermined the laws allowing universities to obtain title to inventions. Courts have clarified that the Bayh-Dole Act neither permits a university to unilaterally claim title to inventions nor automatically vests title to universities. Inventors must assign inventions to explicitly convey title, and if challenged, the use of inadequate assignment language may preclude conveyance. Furthermore, the recent switch from a first-to-invent to a first-to-file patent system may cause confusion with respect to timelines for electing title, disclosure of inventions, and timely filing of patent applications.

This research thesis included a study to investigate and analyze university practices for drafting patent assignments and setting disclosure timelines. Ninety university technology transfer professionals were surveyed with both closed questions for qualitative analysis and contingency questions for coding and evaluation to assess risk of patent protection loss.

The results of the study suggested that many university technology transfer offices mistakenly rely on Bayh-Dole provisions to create an automatic right to patent ownership and provide disclosure guidelines for patentable discoveries. There is an indication that, to varying degrees, university patent owners are at risk of losing ownership rights by not using optimal assignment language. Current disclosure practices indicate a risk due to

late disclosure and election of rights, which could potentially lead to the late filing of applications and permanent loss of patent protection.

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Chapter 1

Introduction

According to *The Economist*, the Bayh-Dole Act was “possibly the most inspired piece of legislation to be enacted in America over the past half-century (Editorial, 2002, par. 2).” The Bayh-Dole Act, codified at 35 U.S.C. § 200-212 and implemented by 37 C.F.R. 401, removed ownership rights to patents derived from federally-funded research from the federal government and placed them into the hands of the contractor, i.e., small businesses and nonprofits (including universities) that performed the research. The result of this ownership transfer was widespread commercialization of new science and technology and the ability of researcher/inventors to benefit from their innovation (Ibid, par. 5).

Contractor ownership rights are conditional, and several obligations must be met to avoid loss of right to the technology. Among the obligations of the contractor is to provide notification to the funding agency of any inventions (disclosure), and to make timely election of title. Furthermore, when a contractor elects to retain title to an invention, vesting is not automatic. For ownership to transfer to the contractor, it must be transferred by assignment from the inventor to the contractor (O’Reilly and Kacedon, 512).

For decades after the Bayh-Dole Act was enacted, universities operated with confidence that their right to patent ownership was incontrovertible. In 1991 and 2011, however, two landmark cases were decided that threatened that concept by challenging the type of assignment agreements that universities entered with their researchers. In each case, the university in question was denied the right to patent ownership due to

insufficient assignment language in employee agreements, and outside contracts containing binding assignment language. The court “decision[s] [highlight] the importance of not only obtaining an effective assignment from employees but also monitoring outside agreements entered into by such employees (Ibid, 513).”

Coupled with the assignment problem, patent reform in the form of the Leahy-Smith America Invents Act was signed into law in 2011. This Act, known as the America Invents Act or AIA, switched the United States patent system from a “first to invent” to a “first to file” system. A significant feature of this change is that the new system necessitates a rush to file a patent application prior to a similar filing (intervening prior art) by another inventor (Guttag, 2011). The “grace period” allowed by the AIA from inventor publication to filing is shorter than the time requirements set forth in the Bayh-Dole Act for disclosure of inventions to the funding agency and the timeline for electing to retain title. The danger to universities is the potential for the illusion of having more time to file an application than exists (Ibid).

In this thesis, current literature is reviewed to illustrate and evaluate the necessary use of binding assignment language and timely disclosure practices to protect university ownership rights to inventions created from federally funded research. The study assesses the practices of university offices of technology transfer and their approaches to the issues presented by the landmark court cases and the changes presented by the America Invents Act.

The Bayh-Dole Act

Background

From the late 1940s to the early 1970s, the U.S. economy enjoyed a period of high economic growth, low unemployment, and minimal inflation. During the 1970s, however, the opposite occurred. The economy suffered two separate energy crises, high inflation and a sharp rise in unemployment. American manufacturing declined, and U.S. productivity became uncompetitive on an international scale (Reuss, 2009). The U.S. imported foreign manufactured goods at an unprecedented rate, resulting in a \$5.8 billion trade deficit by 1978 (Bayh, 2010).

Senator Birch Bayh's 1979 Senate Report No. 480 (cited in Bayh, 2010) identified the "fragmented federal technology policy" as a contributing factor to the United States' lack of productivity. Bayh found that the government was spending large sums to fund research and development by small businesses and by universities and patenting the resulting discoveries. Those discoveries, however, were not being marketed.

In 1979, when Senator Bayh presented his Senate Report, the government owned 28,000 patents created from federally funded research but failed to develop more than 95% of them (Ibid, at (6)). Government funding policies created additional problems. Each funding agency had its own controlling policy, often conflicting with those of other agencies and providing "inconsistent and incoherent" oversight for funded research (Ibid).

The Act

Senator Bayh, along with Senator Robert Dole saw in the research enterprise an opportunity to coordinate patent transfer policies among agencies and at the same time,

promote university-industry relationships, increase commercialization of products, create jobs, and stimulate the economy. The senators introduced the University and Small Business Patent Procedures Act, more commonly known as the Patent and Trademark Law Amendments Act, or the Bayh-Dole Act (the Act), and changed the landscape of university research.

Codified at 35 U.S.C. § 200-212, the Bayh-Dole Act provides uniform oversight of federally-funded research by small businesses or nonprofit organizations. The stated objective was to permit American small businesses and nonprofits (including universities) to elect to retain title to inventions created in federally-funded research. Exceptions to this rule are businesses located outside the United States, under the control of a foreign government, or when the technology presents an issue involving national security.

The United States Code (U.S.C.) sets forth university patent ownership rights under 35 U.S.C. 202. Under this section, requirements for research contracts between federal funding agencies and small businesses or nonprofits are laid out. In relevant part, the requirements state that the contractor (business or nonprofit organization) must disclose each subject invention to the funding agency within a reasonable time after invention (35 U.S.C. § 202(c)(1), LexisNexis, LEXIS through PL 115-22, approved 4/3/17). The contractor must elect title, in writing, within two years of disclosure, or within additional time if allowed by the funding agency (Ibid at (2)). Contractors must file a U.S. patent application prior to the expiration of one year, and timely file corresponding foreign counterparts to that same U.S. application, and if not, allow the Federal Government to do so (Ibid at (3)), and the Federal Government shall have a “nonexclusive,

nontransferable, irrevocable, paid-up license to practice” the invention worldwide (Ibid, at (4)).

The years since the passing of Bayh-Dole have embodied an unprecedented era of invention commercialization which has had a profound impact on the United States economy in that thousands of new companies and millions of jobs have been created, and countless new products have entered the market (Kappos, 2010). New fields of study have advanced, e.g., biotechnology and information communications, as a direct result of the Act (Ibid).

Since the enactment of the Act, tens of thousands of U.S. patents have been issued to Institutions of Higher Education (Source: LexisNexis TotalPatent®, 2017). In 2016 alone, 6,023 U.S. patents were granted to American colleges and universities, and 8,824 new U.S. patent applications were filed by American colleges and universities (Ibid).

Chapter 2

Literature Review

Introduction

Landmark Cases

The Bayh-Dole Act created a reversal of assumptions regarding patent ownership (MIT, 2010, 7). Prior to the Act, agency policies stated that the government retained the right to hold patents on federally-funded inventions. In contrast, Bayh-Dole provided an all-inclusive system under which it was assumed that going forward universities would be the holder of such patents (Ibid). Since Bayh-Dole was enacted, that assumption has been undermined by two landmark cases, *FilmTec Corp v. Allied-Signal, Inc.* 939 F.2d 1568, (1991) (*FilmTec*) and *Brd. of Trs. of the Leland Stanford Junior Univ. v. Roche Molecular Sys.*, 563 U.S. 776 (2011) (*Stanford v. Roche*) that challenge standard language used in assignment agreements and overturn the fundamental presumption that a university shall automatically retain ownership rights to subject inventions.

Patent Reform

Patent reform under the *Leahy-Smith America Invents Act*, 112 P.L. 29, 125 Stat. 284 (2011) (the America Invents Act, or AIA) has changed the U.S. patent system from a ‘first to invent’ system to a ‘first to file’ system. In a ‘first to invent’ system, the problem of conflicting patent applications would be decided by whichever invention could be proven to have occurred earlier (Roberts, 2013, par. 4.). Conversely, in the ‘first to file’ system, the prevailing application is that which is filed first with the U.S. Patent and Trademark Office (Ibid, par.3). For purposes of this review, the significance of this change lies in the necessity of rushing to file patent applications. Following the timelines

set forth in the Bayh-Dole Act (e.g. a university waiting two years after invention to elect title) could potentially allow another inventor time to file a similar patent first.

This review will identify and discuss the cases and their significance for university technology transfer; and the potential for complications resulting from AIA patent reform.

Cases

Case 1. FilmTec Corp v. Allied-Signal, Inc. 939 F.2d 1568, (1991)

Background

On February 22, 1979, Inventor John E. Cadotte filed a patent application for a “reverse osmosis membrane and method to use that membrane to reduce the concentration of solute molecules and ions in a solution.” Cadotte assigned rights in the application and any resulting patents to FilmTec Corp, a company he founded with three other people in the summer of 1977 and incorporated in September that year.

FilmTec subsequently sued Allied-Signal for infringing the patent. Allied-Signal countered that FilmTec did not rightfully own the patent, and therefore had no legal standing to sue for infringement.

Prior to creating FilmTec, Cadotte and his three partners were employees of the Midwest Research Institute (MRI). MRI conducted government research, much of which was in the field of reverse osmosis membranes. At MRI, the four employees worked under a government contract to “provide research on In Situ-Formed Condensation Polymers for Reverse Osmosis Membranes.” The contract stated that MRI “...agrees to grant and does hereby grant to the Government the full and entire domestic right, title and interest in [any invention, discovery, improvement or development (whether or not

patentable) made in the course of or under this contract or any subcontract (of any tier) thereunder]” (*FilmTec Corp v. Allied-Signal, Inc.* 939 F.2d 1568, (1991) 3).

The invention was made sometime between the organization of the company in 1977 and the date of filing in February 1979. Cadotte left MRI in January 1978. He testified that he had conceived the invention one month later. In turn, Allied-Signal produced a notebook of Cadotte’s that verified that between July and November of 1977, he did combine the two chemicals claimed in the patent while he still worked at MRI.

Decisions

The trial court had decided that even if the invention had been made while Cadotte was employed at MRI, under the contract the government could have no more than equitable title to the patent, thus preventing Allied-Signal’s lack of standing defense. The Court determined that when the assignment of rights is made prior to the invention, it grants an *expectant interest* rather than full title, distinguishing between “employers’ rights to full title after employee invention and employers’ rights to mere equitable title before actual invention (Tresemer, 2012, 366) (emphasis added).”

In turn, the appellate court reasoned that

“In our case, the contract between MRI and the Government did not merely obligate MRI to grant future rights, but expressly granted to the Government MRI’s rights in any future invention. Ordinarily, no further act would be required once an invention came into being; the transfer of title would occur by operation of law. If a similar contract provision [**15] existed between Cadotte and MRI, as MRI’s contract with the Government required, and if the invention was made before Cadotte left MRI’s employ, as the trial judge seems to suggest, Cadotte would have no rights in the invention or any ensuing patent to assign to FilmTec. (*Filmtec Corp. v. Allied-Signal, Inc.*, 939 F.2d 1568, 1573 (Fed. Cir. 1991)).

Discussion

While the Courts in the FilmTec case did not decree who the ultimate owner of the patent was, they did make a distinction between the assignment of *full title* and the *expectant right of interest* in a patent. FilmTec determined that “[a]n assignor stating that he “assigns” a future interest is simply conveying a promise to assign in the future (Ghosh, 2016 1),” thus requiring subsequent assignment to effectuate an actual transfer.

The phrase, “agrees to assign and does hereby assign,” however, may be construed as a “*present* assignment of a *future* interest (Ibid, 1)”. The lack of an existing contract between MRI and Cadotte, using the “and does hereby...” language, likely would have cost MRI full ownership rights transferred from Cadotte to MRI, and then from MRI to the government.

Case 2. Board of Trustees of the Leland Stanford Junior University. v. Roche Molecular Systems. 563 U.S. 776 (2011)

Background

In 1985, a California research company called Cetus developed a technique for quantifying blood levels of HIV, the virus that causes AIDS. Three years later, Cetus began collaborations with the Stanford University Department of Infectious Diseases to test new drugs to treat AIDS.

Around that same time, Dr. Mark Holodniy began his tenure with the university.

Dr. Holodniy signed an agreement that he “agree[d] to assign” to Stanford his “right, title and interest in” inventions resulting from his work at the university. As part of his research at Stanford, Dr. Holodniy’s supervisor arranged for him to work at Cetus to learn their methods. Dr. Holodniy’s access to Cetus was contingent upon his signing an

agreement stating that he will “assign and do hereby assign” his “right, title, and interest in ...the ideas, inventions, and improvements” to Cetus.

While at Cetus, Dr. Holodniy developed an invention for measuring the amount of HIV in blood. When he returned to Stanford, the Stanford team tested the invention, which resulted in Stanford acquiring three patents on Dr. Holodniy’s invention.

Cetus was acquired by Roche Molecular Systems in 1991. Roche conducted trials on Cetus’ procedures and commenced marketing and selling HIV test kits that incorporated the technology utilized in the joint research between Stanford and Cetus.

The suit proceeded as follows:

a) The Board of Trustees at Stanford filed suit claiming that Roche had infringed the three patents that they owned on Dr. Holodniy’s invention.

b) Roche counter-claimed that Holodniy’s assignment agreement with Cetus gave made it a co-owner of the invention and that Stanford lacked standing to file suit as owner of the patent;

c) Stanford counter-claimed that Dr. Holodniy had no right to assign the invention to Cetus, claiming that it had followed all procedures to retain title pursuant to the Bayh-Dole Act. It had presented timely notice to the NIH of its intent, properly filed the patent applications. The university further claimed that it had a superior right to ownership pursuant to the Bayh-Dole Act.

Lower Court Decisions

The District Court agreed with Stanford, holding that pursuant to the Bayh-Dole Act, Dr. Holodniy had no right to assign his invention to Cetus.

The case was appealed to the Court of Appeals for the Federal Circuit, where the Court followed the FilmTec decision, concluding that the agreement in which Holodniy “agreed to assign” all interest to Stanford merely constituted a *promise to assign at a future date*. In contrast, the agreement wherein he “agree[d] to assign and d[oes] hereby assign” rights to Cetus did effectively transfer rights to the inventions, and therefore Roche would prevail with its claim that Stanford had no standing to sue. The Federal Circuit Court also held specifically that an inventor’s rights to a federally-funded invention are not automatically voided due to the Bayh-Dole Act, nor does the Bayh-Dole Act give contractors authorization to unilaterally demand title (Bd. of Trs. v. Roche Molecular Sys., 563 U.S. 776, 131 S. Ct. 2188 (2011)).

Supreme Court Case

Stanford appealed the case to the Supreme Court. For those proceedings, 20 interested parties filed amicus curiae briefs, some in support for either party, and some as neutral parties.

The amici curiae positions generally fell in a line consistent with how they would be affected by the outcome of the case. For example, the American Association of University Professors argued against the idea that faculty members are merely employees who are “hired to invent (Amicus Brief for Respondent, Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, No. 09-1159, *11 (December 23, 2010) (available U.S. S. Ct. Briefs LEXIS 113)).”

Large industry leaders argued that to rule in favor of Stanford would threaten collaboration between universities and industry, where “patent rights are particularly important [in fields where] product development times are lengthy, and development

costs are large (Biotech Industry, Amicus Brief for Respondent, Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, No. 09-1159, *4 (December 23, 2010) (available U.S. S. Ct. Briefs LEXIS 139)).”

Birch Bayh, an original author of the Bayh-Dole Act, submitted his brief in support of Stanford, stating that it was the intent of the drafters of Bayh-Dole to create a clear hierarchy of patent ownership rights. In the hierarchy, contractors (including universities) have first option to retain title to all subject inventions. Second, when a university fails to do so, the government may then elect to retain title. Third, under the limited circumstances that the university and the government both choose not to exercise their rights to title, the inventor may then exercise his “provisional, subordinated” ability to obtain title (Bayh, Amicus Brief for Petitioner, Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, No. 09-1159, *5 (December 23, 2010) (available U.S. S. Ct. Briefs LEXIS 2395)).

Supreme Court Decision

The Supreme Court affirmed the Federal Circuit ruling in a 7-2 decision. Chief Justice Roberts delivered the opinion affirming the Circuit Court’s opinion and adding that a) The basic principle stating that inventors have rights to patent their inventions has not changed; and b) The language in the Bayh-Dole Act stating that a contractor may “elect to retain title” does not expressly vest title to universities. Justice Roberts further reasoned that “universities typically enter into agreements with their employees requiring the assignment to the university of rights in inventions. With an effective assignment, those inventions--if federally funded--become “subject inventions” under the Act, and the statute as a practical matter works pretty much the way Stanford says it should. The only

significant difference is that it does so without violence to the basic principle of patent law that inventors own their inventions (Bd. of Trs. v. Roche Molecular Sys., 563 U.S. 776, 793, 131 S. Ct. 2188, 2199 2011).”

There were one concurrence and one dissent following the ruling. The dissent was written by Justice Breyer, followed by Justice Ginsburg. While Justice Breyer did not argue against an inventor’s fundamental right to his inventions, he would have preferred more discussion in the lower courts with respect to university employee’s obligation to assign inventions. He also questioned the application of the *FilmTec* decision to this case, suggesting that there was minimal difference between the two versions of assignment language (Bd. of Trs. v. Roche Molecular Sys., 563 U.S. 32, 131 S. Ct. 2188, 2199 2011).”

Justice Sotomayor wrote the concurrence in agreement with the decision, but she cited concerns about the application of the *FilmTec* language to Bayh-Dole agreements (Bd. of Trs. v. Roche Molecular Sys., 563 U.S. 32, 131 S. Ct. 2188, 2199 2011).”

Discussion

By “shift[ing] the source of federal contractors’ rights from statutory to contractual (Tresemer, 2012, 368),” the Supreme Court decision has placed added responsibility in the contractor/university’s hands. “Institutional IP policies that required faculty to “promise to assign” IP rights at a future date could be trumped by later-in-time agreements that faculty might wittingly or unwittingly sign with third parties (as Holodniy did with Cetus) in which they “hereby assign” their IP rights to a third party (Hayter and Rooksby, 2015, 278, 279).”

The onus is on the universities to reconsider their standard policies and assignment practices, and “draft better employment agreements that assign patent ownership rights in an active manner at the start of employment (McCabe, 2011 par 7).

Patent Reform: The America Invents Act

On September 16, 2011, President Obama signed the Leahy-Smith America Invents Act (AIA) into law. The AIA changed the U.S. patent system from a “first to invent” to a “first to file” system. There are three parts most relevant to this research. First, a person may be entitled to a patent if the same invention has not already been filed, published, on sale, in public use, or otherwise publicly available before the filing date of the invention (35 U.S.C.S. § 102 (LexisNexis, Lexis Advance through PL 115-22, approved 4/3/17).

Second, the AIA has a “grace period” provision. This is the exception that if the disclosure is made by the inventor within a year before filing, it does not preclude patenting. Aside from that narrow exclusion, any time that passes from the invention date to the filing date accrues danger of intervening prior art (Guttag, 2011, 2).

Third, of concern is the fact that the Bayh-Dole compliance requirements are somewhat misleading when viewed from a first to file perspective. Waiting two years from disclosure to elect title, for instance, may be permissible pursuant to Bayh-Dole but leave the invention vulnerable to intervening prior art (Ibid, 2).

Chapter 3

Problem Statement

In the wake of decisions such as *FilmTec v. Allied-Signal* and *Stanford v. Roche*, the use of traditional assignment language (e.g. “agree to assign”) in research agreements has been proven to be insufficient to secure university ownership of subject inventions. The preferred language (i.e. “hereby assign”) is necessary to constitute an actual, rather than promised, conveyance.

The new “first to file” U.S. patent system requires early filing of applications to secure patent protection. Sole reliance of the timelines set forth in the Bayh-Dole Act (e.g. the two-year allowance for election of title) may falsely convince university technology transfer professionals that any new inventions are automatically protected for a two-year period.

Literature in the field of university technology transfer addresses these specific problems presented by court decisions and patent reform, but provides limited if any data detailing current university efforts to overcome them (Hayter and Rooksby, 2015, 278 and Hagelin 2012, 8).

The author of this paper conducted a study of university technology offices to gather and discuss such data and contribute to known information in this field.

Chapter 4

Methodology

This section describes the Design, Procedures, Study Participants, Ethical Issues, Data Management, Result Analysis, and Limitations of this study.

Design

This study was designed to evaluate the policies and practices of university technology transfer offices with respect to the specific problems outlined in the Problem Statement. The study consisted of a survey questionnaire including five closed questions for qualitative analysis and three contingency (follow-up) questions to be coded and analyzed based on risk of losing patent protection. Responses to contingency questions have been assigned a “risk code” from 1) Low Risk, 2) Low to Moderate Risk, 3) Moderate Risk, 4) Moderate to High Risk, and 5) High Risk.

This survey method was selected because a) it permits widespread access to the targeted participants in a short time period; b) because access to personally identifiable information can be controlled, it protects the safety of the participants; and c) it allows the respondents to participate with ease and at their convenience.

Procedures

The questionnaire was prepared and distributed using the web-based Google Forms platform. The platform was selected for ease and clarity in questionnaire preparation, collection of data, basic tallying of data such as number of respondents and percentage breakdown, and for password-protected storage of data during and after completion of the project. Participants were asked to complete the survey provided through a hyperlink.

The hyperlink led directly to the questionnaire in Google Forms and remained active for four weeks.

Delivery of the survey hyperlink was performed via direct e-mail list purchased from Exact Data, a direct-marketing firm specializing in compiling postal, email, and telephone lists; and via the Association of University Technology Managers® (AUTM) listserv discussion board. This means of distribution was appropriate for this study because a) participants are located at universities across the United States, and online access is the most reasonable means by which to reach them; and b) the target population is highly specialized by profession and is most likely to be reached through an organization catering to that professional specialty.

Study Participants

This study targeted a specialized population. Only technology transfer professionals employed in U.S. universities or colleges were invited to participate. E-mails were sent only to directors or managers of technology transfer offices, offices of commercialization, or university patent offices, and participants in the AUTM listserv discussion board e-mails.

This population was appropriate for this study because participants were asked specific, nuanced questions regarding policies and practices exclusive to university technology transfer offices. The general population would not be able to provide educated responses to the survey questions.

The survey was a convenience sample (Thofson, citing Mertens, 2010), sent to an unknown number of recipients. The research was designed for at least 25 respondents.

Ethical Issues

Prior to commencement of research, the author of this study contacted The Johns Hopkins Homewood IRB (HIRB) via the eHIRB application portal to request approval to proceed with the survey. After application and review, HIRB determined that the research contains only non-private information and does not require HIRB approval.

In the survey e-mail script (see Appendix B), participants were requested not to disclose any personally identifiable information and to only submit information that the respondent is authorized to disclose.

No individual respondents or respondent institutions are identified in this study.

Data Management

All collected data will be maintained in strict compliance with The Johns Hopkins University record retention policies.

Survey Model

The study was a convenience model (Thofson, citing Mertens, 2010). Participation invitations were sent to an unspecified number of recipients by the fastest and most widespread means possible. A total of 90 participants responded to the survey. Not all respondents responded to each question in the survey.

Chapter 5

Survey Results and Discussion

Because the number of invitees is unknown, the size and nature of the respondent institutions will be estimated in terms of annual research spending. The respondents were asked to rank their institutions' annual spending by selecting one of the following four categories: Less than \$100 million per year, \$100 million to \$500 million per year, \$500 million to \$1 billion per year, and over \$1 billion per year (Question 8). To estimate the percentage of respondents in each of these categories, the responses are analyzed in comparison with the historical Rankings by Total R&D Expenditures published by the National Science Foundation for the year 2015.

Table 1. Respondent Annual Spending Compared with 2015 Total R&D Expenditures by Universities.

Amount of Annual Spending	Number of Respondents	Total 2015 Number as Reported by the NSF	Estimated Percentage Per Category (%)
Less than \$100 Million	25	751	3
\$100 Million to \$500 Million	38	98	39
\$500 Million to \$1 Billion	17	33	52
Over \$1 Billion	5	10	50

Source: National Science Foundation, *Rankings by total R&D expenditures*

The number of respondents in the three higher spending categories is significant because it represents a high percentage of the universities and colleges most likely to perform research and in turn file applications for subject patents. Note that there is likely a slight discrepancy between 2015 and 2017 total R&D figures, and that only 85 of 90 survey respondents answered this question.

86 out of 88 (97.7%) of respondents to Question 1 indicated that their institutions had a published policy regarding patentable intellectual property. Only 35 out of 86 respondents require researchers to execute an assignment agreement prior to the commencement of research (Question 2).

In both *FilmTec v. Allied Signal* and *Stanford v. Roche*, the university was denied ownership rights due to inadequate language in a signed patent assignment. In both cases, a “promise to assign” was unequal to those agreements that “hereby assigned” rights. Additionally, the consensus of the literature review is that patent ownership protection requires an executed agreement containing the “hereby assigns” language to securely convey rights to future inventions.

Of the 42 Patent Policies submitted as a response to Question 2, all include an obligation for their researchers to assign, but only 6 contained the language “hereby assigns.” Others provided incentives to transfer ownership rights, such as assignment being a condition of employment (5) and the reservation of the right to initiate “action” against any inventor failing to execute all necessary transfer documents (1).

Question 3 is a contingency, or follow-up to Question 2. The participants were asked what assignment language is standard to agreements signed prior to research. There were 48 responses indicating assignment documents using “agrees to assign” or “hereby

assigns,” patent policies or employment agreements using the same language, or “none of the above” based on the presumption that the institution has automatic ownership right to subject invention.

The responses to Question 3 have been tabulated by their response, and then assigned a “risk code” from 1) Low Risk, 2) Low to Moderate Risk, 3) Moderate Risk, 4) Moderate to High Risk, and 5) High Risk.

Executed agreements using the language “hereby assigns” is the lowest-risk category of all that were provided. Executed agreements using “agree to assign” is deemed a low to moderate risk. This has been given the rank that it has because although the language only represents a promise to assign, it is nevertheless a signed agreement reflecting the intent of both parties. University policies with “hereby assigns” language pose a moderate risk, because while the intent of the university is clear, the intent of the inventor is not. This may pose problems in cases such as *FilmTec*, in which both parties have executed assignments in good faith, but the more precise language prevailed (see *FilmTec Corp v. Allied-Signal, Inc.* 939 F.2d 1568, 1991). Policies which present a variation of “must” or “shall assign” again indicate the university’s wishes, but don’t necessarily constitute a two-way agreement. Finally, the highest risk is taken by the university that presumes the right to ownership and takes no steps to secure it.

Table 2. Language Used in Agreements Prior to Research		
Language Used	Assigned Risk Code (Low to High)	Number of Respondents (%)
“Researcher Agrees to Assign and Hereby Assigns...”	1	33/49 (67)
“Research Agrees to Assign...”	2	6/49 (12)
“Policy or New Hire Paperwork States ‘Hereby Assigns...’”	3	3/49 (6)
“Policy or New Hire Paperwork States ‘Shall Assign...’”	4	4/49 (8)
“No Standard Practice; Presumed Ownership by University”	5	3/49 (6)

Answering Question 4, 73 out of 88 respondents confirmed that their institutions have published policies setting forth terms for the disclosure of patent inventions to the university. Question 5, a contingency or follow-up question to Question 4, addresses university disclosure practices. This is in relation to the problem of disclosing an invention to the university so that a decision may be quickly made with respect to the filing of a patent application. In the new First-to-File patent system, there is little time to waste. If a closely similar invention is filed while disclosure is being considered, the opportunity might have been missed (Quinn, 2016).

The responses to Question 5 have been tabulated by their response, and then assigned a “risk code” from 1) Low Risk, 2) Low to Moderate Risk, 3) Moderate Risk, 4) Moderate to High Risk, and 5) High Risk.

Table 3. Time Limits for Disclosure of Invention to University

Language Used	Assigned Risk Code (Low to High)	Number of Respondents (%)
“Disclosure at time of Conception,” “Promptly”	1	38/73 (52)
“Within 1-60 Days”	2	6/73 (8)
“At a Reasonable Time”	3	9/73 (12)
“Prior to Publication or an event Adverse to Filing”	4	5/73 (7)
“No Time Limit”	5	15/73 (21)

Risk levels 1 and 2 afford the university the most time in which to act as quickly as possible in decision-making regarding investing in patent prosecution. It is a poor choice to require disclosure “at a reasonable time,” considering that reasonableness is indiscriminate. The assumption of this language is that all parties share a definition of the term “reasonable.” The highest risk is taken by those respondents with no established time limit for disclosure to the university. The risk is that, even if the inventor can prove he was first-to-invent, the inventor who first files his application is awarded the patent.

Question 6 asks whether the university policy extends the inventor's duty to disclose inventions conceived at the university to a period after he leaves the university. Out of 70 respondents, 38 (54%) require disclosure post-exit and 32 (46%) do not. This question is relevant to the case study in *FilmTec v. Allied-Signal*. One of the issues of the case was the claim that the inventor created his invention one month after leaving his research institution, although it was proven that the inventor performed research while at the institution that made up a significant portion of the patent claims. The results of university research often continue after a researcher leaves the institution. The university's right to retain ownership should extend as long as there is the potential to patent discoveries made while performing university research.

The final question of the survey pertains to technology transfer professionals having access to in-house attorneys specializing in Intellectual Property. Of 86 respondents, 50 (58%) affirmatively responded and 36 (42%) replied in the negative. The question is appropriate for this study because many offices of technology transfer are staffed by research administrators. While they do not and must not attempt to practice law, these administrators must be able to track and understand landmark cases and statutory and regulatory changes that have profound effects on their work.

Chapter 6

Conclusion

The effects of *FilmTec*, *Stanford*, and patent reform have not proven to be fatal to the Bayh-Dole Act, but they do present challenges for university researchers and technology transfer professionals in terms of assignment and disclosure practices.

The Bayh-Dole Act does not automatically vest title to inventions developed in federally funded research. Universities should construct agreements with careful attention to the tense of the agreement language. Agreements that agree to assign, but do not specify “hereby assign” are merely promises to assign at a later date. These promises may be trumped by later assignments signed by inventors, whether intentionally or unintentionally.

The results of this study suggest that many universities rely on the presumption of automatic patent ownership. A strong patent policy is sufficient in most cases, but as the Federal Circuit Court stated in the *Stanford* case, the Bayh-Dole Act does not give a university the power to unilaterally take ownership of patent rights (*Brd. of Trs. of the Leland Stanford Junior Univ. v. Roche Molecular Sys.*, 563 U.S. 776 2011). The best defense against patent loss is a well-worded assignment agreement that clearly states the intent of all parties.

It is imperative for technology transfer professionals and researchers to acknowledge and remain well within the time constraints for patent filing presented by the new first-to-file patent system. Compliance with the Bayh-Dole provisions for electing title to patents (which are better suited to the old first-to-invent system) does not slow the ticking clock

that begins at first disclosure. Applications must be filed within one year of public disclosure, or the opportunity for a patent will have passed.

The Bayh-Dole Act was indeed an inspired piece of legislation, but it is vulnerable to influences such as those discussed in this thesis. It is necessary to always keep abreast of changes and adjust practices to mitigate risk of loss.

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Appendix1. Original Survey Questions

SURVEY QUESTIONS

Instructions: This survey contains eight multiple-choice or short answer questions. To the best of your knowledge, please select the answers that best reflect the policy at your institution. Please do not include any personally identifiable information in your response. Thank you very much for your time and participation in this survey.

1. Does your institution have a published policy regarding ownership of Patentable Intellectual Property conceived or reduced to practice during sponsored research or resulting from significant use of your facilities?
 - a. Yes
 - b. No
 - c. If yes, would you please provide a link to your policy? _____
2. Does your institution require researchers (faculty, student, visiting, or otherwise) to execute an assignment agreement with respect to Patentable Intellectual Property prior to the commencement of research?
 - a. Yes
 - b. No
3. If the answer to Question 2 is yes, which of the following more closely reflects the language used in your institution's standard assignment agreement?
 - a. Researcher *agrees to assign* all rights to all inventions...
 - b. Researcher *agrees to assign, and does hereby assign*, all rights to all inventions...
 - c. Neither. Please explain _____
4. Does your institution have a published policy regarding disclosure of potential inventions to the University?
 - a. Yes
 - b. No

- c. If yes, would you please provide a link to your policy (if different from your response to Question 1)? _____
5. If the answer to Question 4 is yes, which of the following more closely reflects the language used in your institution's disclosure policy?
- Disclosure is required:
- a. At the time of conception.
 - b. 1-60 days after the discovery.
 - c. Prior to reduction to practice.
 - d. Other. Please explain _____
6. If the answer to Question 4 is yes, does the disclosure obligation continue after the researcher leaves the institution for any reason?
- a. Yes
 - b. No
7. Does your technology transfer office have access to at least one in-house attorney who specializes in Intellectual Property?
- a. Yes
 - b. No
8. Which of the following best describes your institution's annual research spending?
- a. Less than \$100 million per year
 - b. \$100 million to \$500 million per year
 - c. \$500 million to \$1 billion per year
 - d. Over \$1 billion per year

Appendix 2. Original E-mail Script

Hello, my name is (name) and I am a graduate student at Johns Hopkins University. As part of my studies in Research Administration, I am conducting a research study of university offices of technology transfer. In particular, I am collecting information about your standard IP policy, standard assignment agreement language, and invention disclosure policy.

Would you be willing to fill out the eight-question survey about your university IP policy? It is estimated that it will take 5 minutes to complete. Your participation is entirely voluntary, no personally identifiable information will be collected, and you may skip any questions that you don't want to answer. I would ask that you only include information that you are authorized to disclose.

The survey may be accessed by the following link: (link)

Thank you in advance for your participation. If you have any questions or comments regarding this survey, I may be reached at (e-mail).

A Biographical Note on the Author

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