

# Conflicts Between Academic Inventors and Universities Since Bayh Dole Act

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## Abstract

The Bayh-Dole Act was passed in 1980, giving universities title to inventions made with federal funding and not only encouraging but also obligating them to commercialize these inventions. One issue accompanying the Bayh-dole act is the tension over who controls the fruit of the invention created in universities sponsored by government funding. There have been differing opinions on who should own the right to the IP of the inventions created in universities. These differing opinions mainly cover ownership of patentable inventions and intellectual property subject to copyright. These concerns may cause licensing to be delayed, incentives to be mismatched between parties, and barriers to the flow of materials and scientific knowledge that are essential for advancement in science.

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## 1. Introduction

Since the inception of universities globally, their primary objectives have been researching and acquisition of knowledge (Kurt, 2018). Many of the world's most significant discoveries were born through university research. The periodic table, several chemotherapy drugs, google, ultrasound, CAT scans, the Internet, and even Gatorade, amongst others, are all products of university research that impact lives daily.

Usually, the creator or inventor of intellectual property is the one who owns the rights to it. However, disputes over who owns the rights to intellectual property are common in an academic environment. To address this issue, many universities have implemented policies that address faculty ownership issues and have negotiated contracts with outside funding sources that specify the distribution of intellectual property rights.

University policies usually cover all personnel, including faculty, post-doctoral fellows, graduate students, technical staff, and visiting scholars. Employment contracts or IP agreements in universities are binding when it comes to the issue of IP ownership. The employee contracts usually assign property rights in all IP to the University, but a significant share in any revenue earned from such IP is typically given to the inventor(s). These shares typically range from 25% to 50% of royalties. The IP agreements usually cover inventions and creations made in the individual's area and place of employment. For example, if a mechanical engineer invents a better generator for industrial use, during his free time without using the university resources at home, that invention would not be included under the employment agreement.

In some universities, the University's ownership and control of all faculty patent rights is a general condition of employment. Some argue that the use of the university facilities justifies the ownership and control as participation in externally funded research requires that the University own the resulting intellectual property.

Purdue University's policy on IP states that Except in specific cases, Intellectual Property that emerges in any part in the course of employment or enrollment at the University, or during a work-for-hire arrangement or visiting scholar relationship with the University.' Harvard University also adopted a university-wide policy that governs the ownership and handling of intellectual property arising from research and other activities at Harvard. The policy outlines which intellectual property will be owned by Harvard and the rights and responsibilities of Harvard researchers about that intellectual property. Stanford university's Patent Policy also states that 'title to all potentially patentable inventions by members of the faculty or staff (including student employees) in the course of their university responsibilities or with more than incidental use of University resources is assigned to the University, regardless of the source of funding, if any. The University's Copyright Policy, however, gives all rights in copyright to the creator, except in specified cases where the law or sponsored agreements require otherwise.

The University of California, the University system with the highest number of US utility patents, requires all UC employees to disclose to the University any potentially patentable inventions they created while employed by UC (employment agreement). Its IP policy also states that the University owns all IP made by its employees or persons utilizing university resources.

Indiana University IP policy also gives the university ownership of all patentable intellectual property created by anyone using university resources. This includes individuals paid through IU, individuals using

funding administered through IU, or using university laboratory space to make the invention. IU owns University Works, which are copyrighted works created by nonacademic employees, funded by external grants, or commissioned by the University, or with a funding agreement indicating that any copyrights will be considered University Works.

When examining most university IP policies critically, the question of whether a university may keep something it never possessed in the first place arises. Who holds the first rights to innovation in post-Bayh-Dole America? These are a some of the issues the US courts have had to resolve.

## **2. Judicial Precedent On Academic Inventors Or Universities Ownership**

In the case of Board of Trustees of the Leland Stanford Jr. University v. Roche Molecular Systems, Inc., 583 F.3d 832 (Fed. Cir. 2009), cert. Granted, No. 09-1159 (US 2010), The issue that arose was whether an employee of a university receiving government financing may transfer the ownership of an invention without the University's permission or whether the University would still own the invention under the Bayh-Dole Act.

When Dr. Holodniy joined Stanford in 1988, he signed a form agreement with Stanford that recited: "I agree to assign . . . to Stanford" in 1989, Stanford sent him to visit Cetus. He signed another form agreement with Cetus that recited: "I will assign and do hereby assign to CETUS" the rights to the inventions developed due to his access to Cetus's technology. Holodniy granted Stanford the rights to his innovations in 1995. However, Roche had started producing HIV testing kits utilizing the Holodniy technology after purchasing Cetus and the contracts it had with Stanford and its researchers.

In 2005, Stanford sued Roche for violating a patent. Because Roche, through its acquisition of Cetus, was also an owner of Holodniy's stake in the contested patents, Roche argued that Stanford lacked standing to file a lawsuit. One of Stanford's arguments was that because the discoveries were related to federal financing, Stanford had a prior claim to Holodniy's ownership stake under the Bayh-Dole Act. Therefore, when Holodniy pretended to transfer it, he had no current ownership interest to give to Cetus. District court concurred. In an overturning decision, the Federal Circuit determined that Holodniy had an ownership interest in the innovations in 1989 and had given Cetus a transfer of that interest when they signed the Cetus contract.

According to the Federal Circuit, nothing was left to transfer to Stanford, and nothing in the Bayh-Dole Act changed this outcome.

Stanford framed the issue before the Supreme Court as to whether a single inventor could unilaterally revoke a federal contractor university's statutory right under the Bayh-Dole Act in inventions resulting from federally funded research through a separate agreement that purported to assign the inventor's rights to a third party.

Roche posed the question differently, asking whether it is permissible under the Bayh-Dole Act for a private university to invalidate an inventor's otherwise legitimate contractual assignment of his rights unilaterally and retroactively in an invention just because it was partially developed using federal funds. The Supreme Court accepted Stanford's formulation of the issue in its grant of certiorari.

In Galen Suppes v. The Curators Of The University Of Missouri, the Plaintiff was seeking a declaratory judgment that he is the lawful owner of all patentable embodiments encompassed in two provisional patent applications filed in December of 2014." *Suppes v. Curators of the Univ. of Mo.*, Case No. 2:15-cv-04095-MDH, (WD Mo. September 8, 2015).

The Plaintiff, Galen Suppes, is a Professor of Chemical Engineering at the University of Missouri, and William Sutterlin was a former student of professor in the University. In this case, the University of Missouri filed a federal lawsuit against Professor Galen Suppes and William Sutterlin, alleging that they filed multiple patent applications without disclosing them or giving proper ownership rights to the University. The University sought Galen Suppes and William Sutterlin to disclose all inventions while the University employed them. A court declaration that the University owns all those inventions and an accounting of the revenue the two received from the intellectual property licensing or sale.

Plaintiff claims that Defendants, acting on behalf of the University and its Curators, have wrongfully demanded that Plaintiff assigns to the University his inventions—Plaintiff coins the term "Inventive Thought" because the inventions giving rise to the dispute have not yet entered the patent application process.

The University of Missouri argued that Suppes' technology transforming the chemical compounds was developed on MU premises using MU machinery. At the same time, the curators could assert ownership rights in accordance with the UM System's collective norms and regulations because the University employed Suppes at the time.

According to UM System regulations, when a UM System employee invents something, the person must disclose that invention to the curators and assign the rights to the University. Only after, if the curators choose to waive ownership rights, may the employee file patent applications.

The Missouri Court of Appeals upheld a 2017 decision that found a former MU professor liable to the UM System Board of Curators in a decadelong intellectual property case.

In the case of Stern v. Trustees of Columbia Univ. in City of New York, 434 F.3d 1375, 1376–77 (Fed. Cir. 2006), a former medical student at Columbia University sought to be added as co-inventor of the patent for the use of prostaglandins in treating glaucoma. Columbia University owns '353 patent, which is directed towards the use of prostaglandins in treating glaucoma, and Lazlo Z. Bito, a long-time faculty member of the University, is the named inventor of the '353 patent.

In 1980, Stern did one semester of ophthalmology research elective in Bito's laboratory while he was a medical student at Columbia University. During the course of the research, Bito directed Stern to begin his project by reviewing Bito's papers on prostaglandins and intraocular pressure ("IOP"). At that time, Bito had published numerous papers on the effects of prostaglandins on the IOP in various animals, notably rabbits and owl monkeys, and had concluded that rhesus monkeys would be good subjects for further studies on the effects of prostaglandins on IOP. While working on the research in Bito's laboratory, Stern conducted experiments that showed that topical application of a single dose of prostaglandin reduced IOP in rhesus monkeys and cats. Stern's experiments did not prove whether tachyphylaxis would develop in primates, the absence of which is required for successful glaucoma treatment.

After Stern's departure from Columbia, while studying the effects of repeated prostaglandin application on the IOP in rhesus monkeys, Bito conceived the '353 patent in 1982. He applied for the patent in 1982, and it was later issued in 1986.

When Stern found out about the '353 patent, he brought a suit seeking to be added to the patent as a co-inventor. Stern also asserted state law claims for fraudulent concealment, breach of fiduciary duty, and unjust enrichment.

The trial court ruled that each joint inventor must typically have contributed to the conception of the invention in order to establish inventorship since "[c]onception is the touchstone of inventorship." Barr Labs., Inc. v. Burroughs Wellcome Co., 40 F.3d 1223, 1227–1228 (Fed. Cir.1994). According to the judge, Stern "did not understand the claimed invention and did not make the necessary discoveries. Furthermore, it was reported that Bito and Stern did not work together to develop a treatment for glaucoma; instead, Stern just carried out an experiment that Bito had already conducted on various animals, species that Bito had already decided to be suitable models for prostaglandins study. It was decided that Stern's involvement was insufficient to warrant co-inventor status.

*In the case of Yale v Fenn, on-going, 2005.* US District Court, D. Connecticut. Fenn invents a mass spectrometer after being forced by Yale's retirement policy to give up his lab space and graduate student assistance. Fenn later earns a Nobel Prize for his work. Yale declines to pursue patenting and Fenn obtains patents and grants licenses for commercial development. Fenn sues Yale for licensing his invention to another company. Yale countersues Fenn for theft and unjustly profiting from his invention, and Fenn is required to pay Yale more than \$1m. The court finds that Fenn misled Yale on the value of the invention.

Some students and alumni decry Yale's actions: "Vindicating the Yale patent policy' is a poor excuse for treating a Nobel Laureate with a 68-year association with and dedicated service to the University, in such a contemptible manner."

In the case of Univ. of Pittsburgh v. Townsend, No. 3:04-CV-291, 2004 WL 7338343, at \*3 (ED Tenn. December 13, 2004), the matter for determination was whether a university's Patent Policy allows such University to own and control the proprietary rights that result from activities of faculty and students and that the Patent Policy and intellectual rights, including trade secrets and know-how associated with developments by faculty and staff. Defendant David Townsend started working with the University of Pittsburgh as an Associate Professor in the Department of Radiology in the University's School of Medicine in 1993 and was later appointed as a "full" Professor of Radiology in the School of Medicine in February 2000. On January 1, 2003, Townsend left the University and joined the University of Tennessee.

The Co-Defendant Ronald Nutt entered into a joint agreement with Townsend and the University to jointly develop a PET/CT tomograph.

On July 27, 1999, Townsend filed an Invention Disclosure Statement with the University's Office of Technology Management, pursuant to the University's Patent Rights and Technology Transfer Policy (the "Patent Policy"). In the Invention Disclosure Statement, Townsend described the invention as a combined PET and x-ray CT tomograph for clinical use and represented that while the conception occurred in 1991, the first written description of the invention was in the first National Institutes of Health grant. Townsend listed himself as the sole inventor of the disclosed invention and listed CPS and Nutt as potential licensees of the invention.

On October 14, 1999, Townsend and Nutt, through CPS's patent counsel, filed a provisional patent application of a combined PET and x-ray CT tomograph and method for using the same with Townsend and Nutt as co-inventors. On June 12, 2002, both inventors, again through CPS's patent counsel, filed a second patent based upon the initial provisional patent filing made on October 14, 1999.

The University sued both investors on the ground that they did not co-assign the patents to the University. It maintains that under its Patent Policy, it owns and controls the proprietary rights that result from activities of

faculty and students and that the Patent Policy also states that it applies to other proprietary and intellectual rights, including trade secrets and know-how associated with developments by faculty and staff. It argued that as an employee of the University, Townsend was subject to the terms of the Patent Policy as part of his respective employment obligation to the University. Based on these grounds, the University contends that it has ownership rights in the PET/CT scanner and the related research and that the defendants have breached their contracts and agreements with the University to recognize the University's ownership rights in the PET/CT scanner and its associated intellectual property, and the corporate defendants have otherwise sought to interfere with these contractual relationships.

In determining the case, the court held that, as in *Gemel*, the University's action for misappropriation and conversion is substantively similar to its action for copyright infringement. The gravamen of the University's complaint is that the defendants allegedly incorporated specific intellectual property allegedly belonging to the University into the copies of software that are sold in conjunction with the commercial PET/CT scanners. The University does not allege that it owns those copies or that the defendants have misappropriated them. Rather, the University is contending that the defendants are infringing its alleged copyrights in the copies of the software. As such, the misappropriation and conversion claim is identical to the University's alleged exclusive right to copy, to create derivative works from, and distribute the copyrighted materials, as provided for by § 106. *Gemel*, 35 U.S.P.Q.2d at 1025. Therefore, the University's claim for misappropriation and conversion is preempted, and defendant's motion to dismiss Count VI will be granted.

*in Kaswan v. University of Georgia and Allergan (2003)* - While attending the University of Georgia, Kaswan developed Restasis® and obtained a license with Allergan. The licensee Allergan then convinced UGA to covertly monetize the Restasis license by transferring more than \$220 million in royalties back to itself. In order to stop Kaswan from interfering with the monetization event and to prevent her from receiving her portion of the royalties, UGA filed a preemptive lawsuit against her for "Trademark Infringement." Kaswan overcame the trademark claims, but UGA and Allergan triumphed in the monetization case thanks to a summary ruling. UGARF's continual postponements essentially depleted Kaswan's resources of the appeal; the case was finally settled out of court in 2010 when UGARF gave Kaswan her inventor's share of the revenue from the license.

In *Madey v. Duke Univ.*, 307 F.3d 1351, 1352–53 (Fed. Cir. 2002), Madey a tenured research professor at Stanford University had a cutting-edge laser research program that was well-regarded in the scientific community. . In 1988, Madey left Stanford for a tenured position in Duke's physics department and moved his free electron laser ("FEL") research lab from Stanford to Duke in 1989. he FEL lab required a significant amount of equipment, so Duke had to add to its physics building to make room for it. Madey acquired sole ownership of two patents used by some of the FEL lab's equipment while he was a student at Stanford.

Madey served for almost a decade as the FEL lab's director at Duke, and the lab continued to succeed in terms of research funding and scientific advancements. However, a disagreement developed between Madey and Duke, which resulted in Madey's dismissal as lab director in 1997 and his departure from Duke in 1998. After Mandy's resignation, Duke continued to use two of Mandy's lasers which were patented prior to his employment at the University. Madey then sued Duke for patent infringement of these patents and brought various other claims. The Supreme Court declined to consider an appeal from Duke after the Federal Circuit Court of Appeals ruled in Madey's favor.

In the case of *Chou v. Univ. of Chicago*, 254 F.3d 1347, 1353–56 (Fed. Cir. 2001), Joany Chou, Ph.D., sued the defendants for correction of inventorship under 35 USC § 256, seeking to be named as the sole inventor or a joint inventor on the three patents relating to the herpes simplex virus.

The Plaintiff Dr. Chou From 1983 until 1996, worked with Dr. Roizman at the University of Chicago's Department of Molecular Genetics and Cell Biology as a graduate student and later as a post-doctoral research assistant. Three US patents, all of which deal with the herpes simplex virus and its application in an avirulent vaccine, list Roizman as both the sole and co-inventor. On the basis of the three US Patents, he is also identified as an inventor on three overseas applications (collectively, "the foreign applications"). These patents' and applications' inventorship is under question.

Chou claimed that the Defendants refused to name her as an inventor on those patents. In addition, Chou charged the Defendants with fraudulent concealment, breach of fiduciary duty, unjust enrichment, breach of contract, and academic theft and fraud arising out of that refusal to name her as an inventor.

The district court had dismissed Chou's suit for correction of inventorship, holding that she lacked standing to bring the claim based on the fact that she was obligated to assign all inventions to the University, Chou could not claim ownership of any of the patents and, thus, had no standing to seek relief under section 256. Although the Federal Circuit agreed that Chou was obligated to assign her inventions to the University, it concluded that Chou nevertheless had standing to seek correction of inventorship and reversed a district court's holding that a purported inventor of an issued patent lacked standing to sue for correction of inventorship.

The district court had also dismissed Chou's state-law claims against the Defendants for failure to state a claim upon which relief could be granted. The district court had dismissed Chou's fraudulent concealment claim

against all of the Defendants, holding that none of the Defendants had a duty to inform Chou of the status of the patent applications. The Federal Circuit disagreed, holding that Roizman had failed in his duty to advise Chou of applications on which she may have been an inventor. The Court further concluded that Chou had stated a claim for fraudulent misrepresentation against the University and ARCH because Roizman was an agent for those parties, but had failed to state a claim against Aviron because Roizman was not an agent for it.

Similarly, the Court reversed the district court's dismissal of Chou's claim for breach of fiduciary duty. The Federal Circuit ruled that Chou had adequately pled a claim for breach of fiduciary duty against her superior, Roizman, and the University under an agency theory. The Federal Circuit affirmed with respect to Aviron, however, holding that Chou had failed to allege its liability under an agency theory.

The Federal Circuit reversed the district court's dismissal of Chou's claim of unjust enrichment against Roizman, holding that she had adequately alleged that Roizman had unjustly retained the benefit of Chou's research. The Federal Circuit reversed regarding the other Defendants, however, because Chou was obligated to assign her inventions to the University and, thus, those parties would have been enriched by Chou's inventions even if she had been a named inventor.

The Federal Circuit reversed the district court's dismissal of Chou's breach of contract claim against the University, finding that Chou had adequately alleged that the University, in violation of its express policies, had failed to compensate her for her invention. Furthermore, the Court reversed the district court's dismissal of Chou's claim against Roizman for the breach of an implied-in-law contract, holding that Chou's adequate pleading of unjust enrichment satisfied the pleading requirements for the related breach of contract claim.

Finally, the Federal Circuit affirmed the striking of Chou's claim of academic fraud and theft because it was immaterial and redundant to her complaint.

The matter for determination in Regents of Univ. of California v. California Berry Cultivars, LLC, No. 16-CV-02477-VC, 2017 WL 9531948, at \*1 (N.D. Cal. April 27, 2017) is mostly about CBC's right to use the patented and unpatented strawberry varieties Shaw and Larson developed during their time at UC.

Douglas Shaw oversaw the breeding program for strawberries at the University of California for more than twenty years. The program's objective is to create new strawberry types. Over the years, Shaw created a great number of novel and interesting strawberry cultivars in association with Kirk Larson, a fellow UC professor. These variants come in a few different forms: some are unpatented, some are covered by pending patent applications, while yet others have already received patent protection.

Following their retirement from UC in 2014, Shaw and Larson joined a private company called California Berry Cultivars, LLC ("CBC"), where they have continued to create new strawberry cultivars. In 2016, they transferred to CBC all of the rights they had in the varieties they had created at UC, as well as any claims based on those rights and any profits from the patented varieties' sale of licenses.

In May 2017, a Northern District of California jury found that CBC and Shaw had committed patent infringement by using 11 of UC Davis' patented varieties without the University's permission and also interfered in its property interests, according to the complaint.

During that trial, it was revealed that CBC had improperly used UC Davis' and Driscoll's proprietary strawberry varieties in its breeding program.

In addition to patent infringement on the aforementioned strawberry varieties, Driscoll's is fighting CBC and Shaw on interference with Driscoll's contracts with growers and nurseries, interference with Driscoll's property rights and unlawful business practices.

### 3. Summary Of the Judicial Precedent

Following the Supreme Court decision in *Stanford v Roche*, it is clear that Bayh-Dole does not vest title in the University by operation of a notice to the government to "elect to retain title." The case illustrates the paranoia that university administrators have that faculty inventors might downplay the value of an invention in the hope that the University will waive its claim or reassign an invention. If an investor wants title to his or her invention, that is taken as a sure sign that the invention has value, and that someone is willing to pay for a license. Thus, few inventions, unless proven worthless, are ever returned by universities to their inventors, despite procedures in Bayh-Dole for inventors to retain ownership of inventions made with federal support.

If a university owns your invention, there is no "fair use"—if you leave the University, even for another university, you cannot practice your invention, and you cannot teach others to use your invention, without the threat of infringement litigation. No one will work with you under such conditions. If you do not like this result, then get your University's patent policy changed to reflect academic freedom, the true state of the employment relationship concerning scholarship, and freedom to innovate.

University administrative claims to own inventions made by faculty may be based on defective arguments or implementation. This is especially true of claims based on the Bayh-Dole Act, which have been shown to be misplaced, and after 2011, if not qualified, are simply fraudulent. To comply with the standard patent rights clause authorized by Bayh-Dole, a university must implement the (f)(2) agreement, which requires the

University to require its research personnel to make a written agreement to protect the government's interest, including establishing the government's rights in subject inventions. That cannot happen unless the (f)(2) agreement entails a delegation of authority under university policy to permit inventors to sign agreements regarding patent rights or assignment of title. Without the (f)(2) agreement in place, universities are in breach of their federal funding obligations. Thus, what the court applied to Fenn may now be applied as well to university administrators:

*A patent is a property which, when wrongfully obtained, may be reassigned to its rightful owner.*

It may well be that there are many—thousands—of such patents sitting in University administrative databases, patents obtained on inventions for which university administrators claimed a right under Bayh-Dole to take ownership. However, such patents have been wrongfully obtained, and perhaps the time has come for such patents to be reassigned to their rightful owners.

Several factors help to establish who owns a university invention and what rights the University may, or may not, have. These factors include whether (1) there are express or implied agreements to assign ownership, (2) the inventor is employed by the University, (3) the invention was made within the scope of employment, and (4) where and when the invention was made. The policy of any US university must conform to the obligations imposed by the Bayh-Dole Act (Public Law 96-517). The Bayh-Dole Act is intended to promote investment by the private sector in the commercialization of federally funded research discoveries for the public good. It includes preferences for small businesses and for manufacturing in the United States. Under Bayh-Dole, a university is required to file patents on those inventions they elect to own and to encourage collaboration with industry to promote the utilization of inventions.

Rights retained by the government under Bayh-Dole include a nonexclusive license to practice the patent and march-in rights. March-in rights allow the government to "march in" and take over an invention if commercialization of an important invention is not being executed with due diligence by a university or licensee. The government has not, to date, invoked march-in rights, but it is possible that someday march-in rights could be applied. One situation that could warrant such action might be one in which a drug or vaccine is needed to control a pandemic.

Further information. To find out more about the background of Bayh-Dole as well as its implications for university IP policies in the US Noncompete clauses are often included in employment agreements and apply when an employee leaves the company.

#### 4. Conclusion

Although there are issues that sometimes arise from university innovations, an institutional IP policy is a prerequisite for successful collaboration between academia and commercialization partners and without a formal policy regulating the ownership and use of IP rights. The different stakeholders in a university/PRI (researchers, technicians, students, visiting researchers, etc.) and commercialization partners (industrial sponsors, consultants, non-profit organizations, SMEs, governments) will need guidance on how to make decisions concerning IP.

Future research will focus on how universities might use broadly written research exemptions to avoid the problems caused by the Bayh Dole Act. The issue might be resolved by a Bayh-Dole Act amendment. It would return the law to its original purpose. That notion encompassed the exclusive use of patents by universities for their own research.

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