

Expert Analysis

Reaffirming the Inventor's Role In Patent Ownership

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The Supreme Court delivered its opinion in *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems Inc.*, 131 S. Ct. 2188 (June 6, 2011), the first affirmance of a Federal Circuit patent law analysis in years.¹

This was also the first time the court had ever tackled interpretation of the University and Small Business Procedures Act of 1980 (better known as the Bayh-Dole Act, 35 U.S.C. §§ 200-212). At issue was whether the provisions of the Bayh-Dole Act automatically grant ownership of federally funded inventions to research institutions rather than to the inventor.

The Bayh-Dole Act allows research institutions to retain title to inventions funded by federal research money. Since its enactment, the number of patents American universities seek annually has increased tenfold.²

Before the Bayh-Dole Act was enacted in 1980, the federal government had no uniform policy for the ownership of the fruits of the research it funded. Some agencies retained ownership of inventions derived from research they funded. Other agencies allowed institutions to retain ownership of inventions they developed through federally funded research, in exchange for a license granting the federal government permission to use the patented invention.

Each of these approaches had problems. When the government retained ownership, patents were rarely put to use commercially.³ Under the licensing approach, industry had to contend with more than 26 agency policies, which proved a confusing administrative burden.

In response, Congress enacted Bayh-Dole. The act formalized the ownership rights between research institutions (called "contractors" under Bayh-Dole) and the federal government.

Under Bayh-Dole, a contractor can gain ownership of a government-funded invention as long as the contractor meets certain requirements, such as disclosing the invention to the agency and making a written election to retain title to the patent. Otherwise, the government may receive title. In any case, the government retains "march-in

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rights," permitting it, under certain circumstances, to require the contractor to grant a license to a third party.

The wording of the Bayh-Dole Act posed a potential conflict with established federal patent law, however. In *Stanford v. Roche*, the question arose as to how Section 101 of the Patent Act, 35 U.S.C. § 101, fits into the Bayh-Dole framework.

Normally, under the Patent Act, ownership of a patent rests with the inventor. Section 101 says "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent."

What happens, then, if an inventor, exercising rights apparently granted under the Patent Act, assigns his rights to a third party, rather than to the contractor for a government-funded invention? If Bayh-Dole automatically vests ownership in the contractor, an assignment by the inventor is subject to the contractor's superior rights. If the ownership rests with the inventor, however, it appears that an inventor could subvert the framework of Bayh-Dole.

FACTS OF STANFORD V. ROCHE

The three patents-in-suit at issue in the case are directed to methods for quantifying HIV in human blood samples and correlating those measurements to the effectiveness of drugs that fight the retrovirus. The claimed methods use the polymerase chain reaction technique for measuring the level of ribonucleic acid from HIV in the blood of infected humans.

PCR is a common laboratory technique that provides copies of DNA segments for, among other applications, identifying genes or testing for diseases.

In 1988 Stanford University hired Dr. Mark Holodniy as a research fellow to develop a PCR-based screen for HIV. When he was hired, Holodniy signed a "copyright and patent agreement" obligating him to assign his inventions to the university.

The agreement stated the following: "I agree to assign or confirm in writing to Stanford and/or sponsors that right, title and interest in ... such inventions as required by contracts or grants."

Shortly thereafter, and while still employed by Stanford, Holodniy began regular visits to Cetus, a company that developed PCR techniques in the early 1980s. Holodniy also signed Cetus' "visitor's confidentiality agreement," which said "[Holodniy] will assign and do[es] hereby assign to Cetus, [his] right[,] title, and interest in each of the ideas, inventions and improvements" that he may devise from his work at Cetus.

Stanford and Cetus were also parties to "materials transfer agreements" permitting Stanford to use PCR-related materials and information.

In 1991 Roche purchased Cetus' PCR business (including its agreements with Holodniy and Stanford) and began manufacturing HIV detection kits that screened for retroviral RNA.

Stanford filed the parent application to the patents-in-suit May 14, 1992. Holodniy, however, did not execute a written assignment of his rights in that application to Stanford until 1995.

In 2005 Stanford sued Roche in the Northern District of California, alleging that Roche's HIV detection kits infringed its patents. Roche counterclaimed, arguing that Stanford lacked standing to sue for infringement and that Roche possessed an ownership interest in the patents-in-suit.

The District Court construed the patent claims and ultimately held them invalid as obvious on Roche's motion for summary judgment.

THE FEDERAL CIRCUIT DECISION

The Federal Circuit vacated the District Court's order granting Roche's motion for summary judgment on the grounds that Stanford did not have an ownership interest in the patents-in-suit, and therefore, the District Court lacked jurisdiction to address their validity. *Bd. of Trustees of the Leland Stanford Junior Univ. v. Roche Molecular Sys.*, 583 F.3d 832 (Fed. Cir. 2009).

The Federal Circuit first confirmed that the question of ownership of patent rights is "typically a question exclusively for state courts." Pointing to an exception to that rule, however, the court noted that "the question of whether contractual language effects a present assignment of patent rights, or an agreement to assign rights in the future, is resolved by Federal Circuit law."

In order to determine ownership of the patents, the Federal Circuit turned to the language Stanford used in the copyright and patent agreement. Stanford's agreement said "agree to assign." The court held that this meant Holodniy "agreed only to assign his invention rights to Stanford at an undetermined time."

The court noted that in *IpVenture Inc. v. Prostar Computer*, 503 F.3d 1324, 1327 (Fed. Cir. 2007), "[w]e have ruled that the contract language 'agree to assign' reflects a mere promise to assign rights in the future, not an immediate transfer of expectant interests." At best, therefore, Stanford gained only "certain equitable rights" against Holodniy upon execution of the agreement.

On the other hand, Cetus' visitor's confidentiality agreement used the words "I will assign and do hereby assign to CETUS, my right, title and interest in each of the ideas, inventions and improvements." The court held that this meant Cetus immediately gained equitable title to Holodniy's inventions upon execution of the confidentiality agreement. Thus, the court recognized a critical distinction between the somewhat

Reaping the benefits of the Bayh-Dole Act: What you should do

Research Institutions/Contractors	Clearly establish contractor ownership of all inventions made with federal funding.
Companies Working with Contractors	Educate employees on the risks of signing conflicting patent ownership agreements.
Investors/Acquirers/Licensers	Investigate all possible conflicted assignments of patent rights.

passive language of the Stanford agreement and the more immediate language of Cetus' agreement.

The court went on to analyze title to the patents-in-suit, finding that Cetus' equitable title converted to legal title, at the latest, on May 14, 1992, the filing date of the parent application. To support this holding, the court quoted *FilmTec Corp. v. Allied-Signal Inc.*, 939 F.2d 1568, 1572 (Fed. Cir. 1991): "Once the invention is made and an application for patent is filed ... legal title to the rights accruing thereunder would be in the assignee..., and the assignor-inventor would have nothing remaining to assign." Because Holodniy had already assigned his patent rights to Cetus, his written assignment to Stanford in 1995 had no legal effect.

Stanford contended that because Holodniy's research was funded under National Institutes of Health contracts, Stanford's election to retain title under the Bayh-Dole Act meant that Holodniy had rights to the patent only if both the government and Stanford declined to exercise their rights.

The court held that Stanford's interpretation of the Bayh-Dole Act was unsupported by any "reasons or authorities." Accordingly, the act could not void Holodniy's prior assignment to Cetus.

SUPREME COURT CERTIORARI AND BRIEFING

On Nov. 1, 2010, the Supreme Court granted review of the Federal Circuit's decision on whether the Bayh-Dole Act vested ownership rights in the contractor (Stanford), rather than the inventor. The briefs explored both the text of the act and the policy implications of each of the scenarios.

Arguments based on the text of Bayh-Dole

Both Stanford and Roche argued that the text of the act supported their positions. Stanford noted that the act applied to "subject inventions," defined as "any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement."

Stanford said "[s]ince an institution can only create an invention through the actions of its employees, this language is naturally read to include all inventions made by the contractor's employees with the aid of federal funding."

Roche countered that the phrase "of the contractor" does not grant ownership; it merely refers to inventions already owned by the contractor.

Stanford next observed that the act allows the contractor to "retain title to any subject invention" as long as the contractor complies with certain provisions of the act. If these conditions are not met, the government receives title. If the contractor elects not to retain title, the government "may consider and after consultation with the contractor grant requests for retention of rights by the inventor."

Within this framework, Stanford argued, Congress did not intend that an inventor could circumvent the statutory arrangement by assigning away his rights to a patent.

In an amicus brief in support of the Stanford's petition for certiorari, the United States supported Stanford's argument, describing the Bayh-Dole Act as a hierarchy of ownership. At the top is the government, followed by the contractor and, at the bottom, the inventor.

Under Bayh-Dole, a contractor can gain ownership of a government-funded invention as long as the contractor meets certain requirements.

In response to these arguments, Roche answered that the description of the hierarchy is correct, but only for inventions “of the contractor.” Unless an employee assigns ownership rights to the contractor, an invention is not “of the contractor.”

Roche countered with its own textual arguments. It pointed out that in several statutes, Congress explicitly vested ownership in an entity other than the inventor. For example, in statutes superseded by the Bayh-Dole Act, rights to inventions developed under contracts with NASA and the Department of Energy were the property of the United States. Roche’s point was that Congress knew how to draft a statute in which the normal rule of ownership vested in the inventor does not apply. The fact that Congress failed to include explicit language in the Bayh-Dole Act, Roche maintained, meant that a court should not imply it.

Policy arguments

Stanford made several policy arguments in support of its position. The university argued that, under Roche’s interpretation of Bayh-Dole, ownership of patents funded by the government would be permanently clouded. Stanford said if the Federal Circuit’s decision were allowed to stand, a contractor would never know if it had clear title to patents stemming from government-funded research because of the ever-present threat that the inventor had assigned his rights away.

Stanford also argued that the Federal Circuit decision undermined the purpose of the Bayh-Dole Act: to fund research for the public good. To recognize Cetus’ ownership of the patents, Stanford argued, would acknowledge a “loophole” in the Bayh-Dole framework. This loophole, Stanford said, “calls into question the government’s ability to manage federally funded inventions for the benefit of the public.”

Stanford added that the Federal Circuit ruling would be a return to the “bad old days” before the Bayh-Dole Act, when a multitude of agencies and statutes regulated government-funded research. Without the clarity that a contractor university had title to government-funded inventions, Stanford claimed, collaboration between the government, research institutions and business would be chilled.

Roche argued that, before the Federal Circuit ruling, contractors already acted as if patent ownership vested in the inventor. If contractors believed they automatically had rights to inventions, they would have had no reason to make their employees assign inventorship rights. Roche noted several examples of assignment agreements in which the employee assigned his present right, rather than agreed to assign in the future, as Stanford’s assignment contract provided.

Amicus briefs

The case drew widespread attention in the research community. Seven briefs supported Stanford, four supported Roche and one was for neither party. Additionally, at the certiorari stage, four amicus briefs in support of Stanford were submitted.

Predictably, several groups representing the recipients of federal research dollars, such as Massachusetts Institute of Technology, the Wisconsin Alumni Research Foundation and the Association of American Universities, urged the court to adopt Stanford’s position. Aware that the Federal Circuit holding could result in the loss of government-funded inventions due to insufficiently drafted assignment contracts, supporters of Stanford argued that Roche’s position represented a “loophole” circumventing the proper functioning of the Bayh-Dole Act.

The Supreme Court’s decision makes clear that if government contractors intend to reap the benefits of the Bayh-Dole Act, their employees must execute agreements that clearly assign to the contractor any inventions made with federal funding.

Groups representing inventors supported Roche because any rule automatically divesting inventors of their patent rights is contrary to their interests. Industry groups supported Roche because industry sometimes collaborates with research institutions that receive federal funding. They argued that a rule automatically granting patent rights to the contractor would nullify industry's rights to a jointly developed invention.

The American Intellectual Property Law Association made an interesting argument. The AIPLA said Stanford's position would result in a taking of private property without due process or fair compensation, which is contrary to the Constitution. The group also argued that the funding of the patent cannot justify the taking because the government is not paying the inventor but rather the inventor's employer.

Another notable amicus brief was submitted by former U.S. Sen. Birch Bayh, one of the drafters of the act. In support of Stanford, he said Congress chose to give research institutions the "lead role" and that Congress never intended for federally funded patent rights to be predicated on assignments from the inventor. The brief also claimed that Roche's position would compromise Bayh-Dole by allowing inventors to trump the interests of the public and the government.

ORAL ARGUMENT

The Supreme Court heard oral arguments Feb. 28. During Stanford's argument, Justice Samuel Alito asked whether universities had been proceeding on the assumption that the Bayh-Dole Act vested ownership in the contractor rather than the inventor. If ownership automatically vested in the contractor, Alito implied, the assignment of rights to inventions, which Stanford had Holodniy sign, would have been unnecessary. To this, Stanford's counsel did not provide a reasoned response.

Justices Alito and Antonin Scalia pointed out another weakness in Stanford's case. The normal rule is that inventors have rights to their inventions, even if those inventions were made during employment. If Congress wanted to vest ownership rights in the contractor instead of the inventor it should have made that point explicit.

During oral argument, Deputy Solicitor General Malcolm L. Stewart emphasized that if the Federal Circuit decision were allowed to stand, contractor universities and inventors could contract around the act to cut out the government. For example, he said the contractor and inventor might agree to split the royalties from a patent, excluding the government entirely despite its funding. But several of the justices asked why the government could not simply require an assignment to the contractor as a condition of federal funding to guard against this possibility.

During Roche's oral argument, Justice Alito said the statute appeared to assume that the contractor would always have rights to inventions derived from federally funded research. Justice Sonia Sotomayor added there appeared to be no reason Congress would have wanted contractors and inventors to be able to circumvent the government's rights by contracting around Bayh-Dole. Roche's counsel responded that the act governed only the relationship between the contractor and the government.

He said there was no need to regulate the relationship between the contractor and inventor because, before passage of the act, contractor universities had shown they were capable of securing rights in the inventions of their employees.

He also raised the point previously noted by several of the justices: the government could control the inventor-contractor relationship by refusing to fund research unless inventors assigned their rights to their contractor employers.

SUPREME COURT DECISION

The Supreme Court handed down its decision June 6. In an opinion by Chief Justice John Roberts, the court affirmed the Federal Circuit by a margin of 7-2. Justices Stephen Breyer and Ruth Bader Ginsburg dissented.

The court's decision began with the baseline rule that patent rights in an invention vest in the inventor. Citing Congress' authority in the Constitution "[t]o promote the Progress of Science and useful Arts, by securing ... to Authors and Inventors the exclusive Right to their respective Writings and Discoveries," the court observed that in more than 220 years since the Patent Act, this basic rule has remained unchanged.

The court next noted that, in the past, Congress has vested rights in an invention to an entity other than the inventor, such as the government. When it did so, though, Congress was explicit. According to the court, however, language divesting the inventors of their rights is "noticeably absent" from the Bayh-Dole Act.

The court then addressed Stanford's arguments that the language of the act implied that rights to an invention vested in contractors, rather than the inventors. The court said it would be odd for Congress to rely on implication to overturn the general rule of inventors' rights to their inventions. Accordingly, the court rejected Stanford's reading of the statute.

The court also discussed the implications were Stanford's argument to prevail. The act applies to subject inventions "conceived or first actually reduced to practice in the performance of work ... funded in whole or in part by the federal government."

The court declared that, under Stanford's argument, an employee's invention would belong to the contractor even if the invention was conceived prior to the employment, as long as it was reduced to practice during employment. Furthermore, the contractor would gain title to inventions even if only "one dollar of federal funding was applied toward the invention's conception or reduction to practice."

Such a "sea change" in the basic rules of ownership of inventions, the court determined, cannot rise by implication. Even the dissent did not argue for Stanford's position. Instead, Justices Breyer and Ginsburg would have remanded the case to the Federal Circuit to consider two arguments not presented by either party.

First, the Federal Circuit's decision hinged on the difference between Stanford's and Cetus' assignment contract: the "agree to assign" versus "hereby assign" language. The dissent argued that, under the law at the time of Stanford's assignment, there was no distinction between these clauses. According to the dissent, the Federal Circuit modified this law in *FilmTec* but provided no reasoned explanation. The dissent would have had the Federal Circuit revisit the *FilmTec* decision.

Second, the dissent argued that the Bayh-Dole Act could be interpreted to require an assignment of patent rights in federally funded inventions. The dissent noted that Executive Order 10096 requires federal employees to assign their inventions to the government. Because the act and the executive order's objectives were "roughly analogous," the dissent said, they would have remanded the case to the Federal Circuit to consider whether the act required an assignment of inventions to the contractor.

IMPLICATIONS OF *STANFORD V. ROCHE*

The Supreme Court's decision makes clear that if government contractors intend to reap the benefits of the Bayh-Dole Act, they must have their employees execute agreements that clearly assign to the contractor any inventions made with federal funding.

In addition, any company engaged in cooperative research with other entities should educate their employees of the dangers of signing any agreements that would conflict with their invention assignment obligations to the company. In the context of corporate transactions, any potential investor, acquirer or licensee of "bet-the-company" patent rights would do well to conduct a detailed "due diligence" investigation⁴ into possible conflicted assignments of the target inventions.

At this writing, both houses of Congress have passed similar bills that would change the U.S. patent system from a "first to invent" system to a "first to file" system, which would also overturn 220 years of patent law.⁵ The court's focus on the undesirability of massive change to the "norm" of inventors' rights under U.S. patent law and its focus on Congress' limited authority to vest patent rights in "inventors," will likely be the basis of arguments that the proposed first-to-file system could be found unconstitutional.

NOTES

- ¹ The court's last decision affirming both the reasoning and judgment of the Federal Circuit appears to have been *J.E.M. Ag Supply v. Pioneer Hi-Bred International*, 534 U.S. 124 (2001), which related to the patentability of newly developed plant breeds.
- ² *Innovation's Golden Goose*, THE ECONOMIST, Dec. 12, 2002.
- ³ For example, before Bayh-Dole, the government licensed less than 5 percent of its patents to industry. In contrast, by 1998, 63 percent of all university inventions were federally funded, and nearly half of these were licensed to industry. See NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected (July 2001), available at http://www.ott.nih.gov/policy/policy_protect_text.aspx#c.
- ⁴ See *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 208 (1976) (citing 15 U.S.C. § 77k(b)(3)(B)(i)).
- ⁵ See Patent Act of 1790, Ch. 7, 1 Stat. 109-112 (Apr. 10, 1790), at §5 (only "first and true inventor or discoverer" entitled to patent).



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