

Client Alert

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Supreme Court Holds That Bayh-Dole Act Does Not Automatically Strip Employees Of Rights In Their Federally Funded Inventions

On June 6, 2011, the United States Supreme Court issued a decision in *Stanford University v. Roche Molecular Systems* (7-2, with Justices Breyer and Ginsburg dissenting) that clarifies the scope of inventors' rights in federally funded inventions vis-à-vis their federal contractor employers. Affirming the Federal Circuit and rejecting the position advocated by the United States government, the Court held that the University and Small Business Patent Procedures Act of 1980 (the Bayh-Dole Act),¹ does not automatically vest title to federally funded inventions in federal contractors or authorize contractors unilaterally to take title to such inventions. The opinion has implications for federal contractors and companies collaborating with them, particularly in academic-industry settings.

The Bayh-Dole Act

The Bayh-Dole Act (the Act) gives rights in "subject inventions" to federal contractors, defined as "any person, small business firm, or nonprofit organization" party to federal funding.² A "subject invention" is one that the federal contractor "conceived or first actually reduced to practice in the performance of work under a funding agreement."³ Congress enacted the

Act in 1980 to "promote the utilization of inventions arising from federally supported research," §200, such as the commercialization of federally funded inventions through academia-industry license agreements. The Act also provides that a contractor may "elect to retain title to any subject invention."⁴

The *Stanford* Litigation

In 1985, a company called Cetus began to develop methods for quantifying blood-borne levels of human immunodeficiency virus (HIV), the virus that causes AIDS. A Nobel Prize winning biochemistry technique developed at Cetus known as the polymerase chain reaction (PCR) was an integral part of these efforts. In 1988, Cetus began to collaborate with scientists at Stanford to test the efficacy of new drugs to treat AIDS.

Dr. Mark Holodniy joined Stanford as a research fellow in the department around that time. When he did so, he signed an agreement stating that he "agree[d] to assign" to Stanford his "right, title and interest in" inventions resulting from his employment there. Holodniy's supervisor arranged for him to conduct research at Cetus to learn about PCR. As a condition of gaining access to Cetus, Holodniy was

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required to sign an agreement stating that he “will assign and do[es] hereby assign” to Cetus his “right, title and interest in ... the ideas, inventions, and improvements” made “as a consequence of [his] access” to Cetus.

Working with Cetus employees, Holodniy devised a PCR-based procedure for measuring the amount of HIV in a patient’s blood. Upon returning to Stanford, he and other Stanford employees tested the procedure. Stanford secured three patents to the measurement process. Roche Molecular Systems acquired Cetus’s PCR-related assets. After conducting clinical trials on the HIV quantification method developed at Cetus, Roche commercialized the procedure, and its HIV test kits are now used worldwide.

In 2005, Stanford filed a patent infringement suit against Roche, alleging that Roche’s HIV test kits infringed the three patents that came out of Dr. Holodniy’s research. Roche responded in part that the agreement between the Dr. Holodniy and Cetus gave Roche co-ownership of patent rights, extinguishing Stanford’s standing (because co-owners of a patent normally must join in an infringement suit). Stanford countered that, because its relevant research was federally funded, the university had superior rights under the Bayh-Dole Act, such that Dr. Holodniy had no rights to assign to Cetus in the first place.

The district court held that although Dr. Holodniy had assigned his rights in the patented inventions to Cetus, the Act allows an individual inventor to obtain title only if the federal contractor and government decline to take title to the rights. Because Stanford had taken title to the patent rights, Dr. Holodniy had no rights to assign to Cetus.

The Court of Appeals for the Federal Circuit reversed. The Federal Circuit first applied California contract law principles and found that the “agree to assign” language in the Stanford

agreement was merely a promise to assign future rights, whereas the “do hereby assign” language of the Cetus agreement was a present assignment of future rights. Interpreting the Act, Federal Circuit also found that Roche had a co-ownership interest and that Stanford therefore lacked standing.

No Automatic Vesting In Federal Contractors

Writing for the seven-Justice majority, Chief Justice Roberts first observed that “[s]ince 1790, the patent law has operated on the premise that rights in an invention belong to the inventor.”⁵ Accordingly, an employer normally does not have rights in an employee’s invention absent an agreement to the contrary. The Court held that the Act did not alter this norm by automatically vesting title to federally funded inventions in federal contractors such as Stanford.

The Act confers rights in federally funded “subject inventions” to “any person, small business firm, or nonprofit organization that is a party to a funding agreement.”⁶ A “subject invention” is “any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement.”⁷

Focusing principally on policy and congressional purpose, Stanford (supported by the United States as *amicus curiae*) argued that the Act vests title to federally funded inventions in the inventor’s employer, the federal contractor, when the invention is conceived or first reduced to practice with federal funding.⁸

The Court rejected those arguments, observing that Stanford’s interpretation “assumes that Congress subtly set aside two centuries of patent law in a statutory definition,” and renders the phrase “of the contractor” superfluous, since the definition already covers inventions made under a funding

agreement. Construing that phrase to refer instead to a subset of inventions conceived or reduced to practice under a funding agreement makes the phrase meaningful, the Court reasoned. And, the Court observed, “invention owned by the contractor” or “invention belonging to the contractor” are more natural readings of the phrase.⁹

The Act also states that federal contractors may “elect to retain title.” Stanford and the United States argued that that phrase implies that the contractor also may elect to “acquire” or “receive” title, and thus essentially provided contractors with an unilateral “option” to take title from inventors. The Court rejected that argument, finding instead that the phrase confirms that the Act does not itself *vest* title in contractors. The Court observed that the ordinary meaning of “retain” is to possess or continue to possess something you already have, and does not additionally authorize a contractor to “acquire” title in the first place.¹⁰

The Court found additional support for its interpretation in the “limited scope” of the Act’s procedural protections, which expressly give contractors the right to challenge a Government-imposed impediment to retaining title to a subject invention,¹¹ but do not provide similar protection for inventors or third parties.¹² The Court reasoned that this absence of protections “makes perfect sense” if the Act applies only when a contractor already possesses title to an inventor’s interest.¹³

Justice Breyer, joined by Justice Ginsburg, dissented. They agreed with the majority that the term “invention of the contractor...covers those employee inventions that the employee properly assigns to the contractor, *i.e.*, his or her employer.”¹⁴ But they disagreed with the majority’s conclusion “that the individual inventor can lawfully assign an invention (produced by public funds) to a third party, thereby taking that invention out from under the Bayh-Dole Act’s restrictions,

conditions, and allocation rules.”¹⁵ “That conclusion,” they fear, “may significantly undercut the Act’s ability to achieve its objectives” — as the United States argued — because “[i]t allows individual inventors, for whose invention the public has paid, to avoid the Act’s corresponding restrictions and conditions.”¹⁶

Possible Implications of the Decision

As the Court noted, this ruling had the potential to work a “sea change” in the law, but may not have much of an impact after all. As the Court observed, its construction of the statute appears to be consistent with the common practice of contractors, who generally obtain assignments from their employees. It also is consistent with the common practice (and in some cases, the rules) of agencies that fund federal contractors (including the National Institutes of Health, or NIH, the agency that granted the federal funds at issue in the case), who typically expect those contractors to obtain such express assignments. “With an effective assignment,” federally funded inventions become “subject inventions,” and the Act “as a practical matter works pretty much the way Stanford says it should.”¹⁷ The primary impact of the decision, then, may be an increased focus by federal contractors on ensuring that they obtain “effective assignments,” through a more careful review of the language in the agreements that researchers sign as part of their employment at the contractor, as well increased scrutiny of the agreements those same researchers may sign with third-party collaborators. As a practical matter, because such collaborations are often mutually beneficial, the decision may also encourage more express negotiations between research institutions and third parties, which may result in some cases in express agreements establishing co-ownership of the intellectual property that arises out of that collaboration.

Endnote

- ¹ 35 U.S.C. §§200-212.
- ² 35 U.S.C. §§201(e), (c), 202(a).
- ³ §201(e).
- ⁴ §202(a).
- ⁵ (Slip op. at 1.)
- ⁶ §§201(e), (c), 202(a).
- ⁷ §201(e).
- ⁸ (Slip op. at 8.)
- ⁹ (*Id.* at 10.)
- ¹⁰ (*Id.* at 11.)
- ¹¹ §202(b)(4)
- ¹² (*Id.* at 13.)
- ¹³ (*Id.*)
- ¹⁴ (Dissent at 1.)
- ¹⁵ (*Id.* at 5.)
- ¹⁶ (*Id.*)
- ¹⁷ (Slip op. at 15.)

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