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Federal Government Contractors and Grantees Should Take Steps To Protect Their Patent Rights After the U.S. Supreme Court Decision in Stanford v. Roche

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On June 6, 2011, the U.S. Supreme Court decided *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc., et al.*, 563 U.S. ____ (2011) (the "<u>Stanford v. Roche decision</u>"), settling a patent infringement dispute involving conflicting interpretations of the University and Small Business Patent Procedures Act of 1980, Pub. L. No. 96-517, 94 Stat. 3015 (codified as amended at 35 U.S.C. §§ 200-212) (the "Bayh-Dole Act"). In relevant part, the Bayh-Dole Act establishes rights of the federal contractor and the federal government in connection with a federally funded invention, and allows certain federal contractors to retain title to federally funded inventions. As explained below, this Supreme Court decision has significant implications for federal government contractors and grantees, and requires them to take certain steps to protect their rights in federally funded inventions.

In *Stanford v. Roche*, the Supreme Court affirmed the U.S. Court of Appeals for the Federal Circuit decision that allowed a Stanford University employee inventor to transfer title to a federally funded invention to a third party, Roche Molecular Systems, Inc., rather than find that title had vested in either Stanford University as the federal contractor performing the research, or the federal government. Stanford received federal funding for its Human Immunodeficiency Virus ("HIV") research through its contract with the National Institutes of Health ("NIH"). The Stanford employee inventor involved in this research had signed a "Copyright and Patent Agreement" agreeing to assign rights in future inventions to Stanford. Subsequently, the same employee signed a "Visitors Confidentiality Agreement" ("VCA") making a present assignment to Cetus (which was later purchased by Roche Molecular Systems) of rights in future inventions that might arise during his collaboration with Cetus as a Stanford employee. As a result of that research, Stanford notified the NIH pursuant to the Bayh-Dole Act that it intended to retain title to its inventions, and then subsequently obtained three patents.

The patent infringement dispute arose when Stanford sued Roche for selling HIV detection kits that infringed on the Stanford patents. Roche countered that the Stanford employee inventor had transferred his rights in the HIV research via the VCA and that the Stanford patents were invalid. Stanford unsuccessfully argued that it had title to the federally funded HIV research pursuant to the Bayh-Dole Act.

In interpreting the Bayh-Dole Act in Stanford v. Roche, the Supreme Court found the following:

Nowhere in the [Bayh-Dole] Act is title expressly vested in contractors or anyone else; nowhere in the Act are inventors expressly deprived of their interest in federally funded inventions. Instead, the Act provides that contractors may "elect to retain title to any subject invention." 35 U.S.C. §202(a).

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We have rejected the idea that mere employment is sufficient to vest title to an employee's invention in the employer.

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[The Act] does not displace an inventor's antecedent title to his invention. Only when an invention belongs to the contractor does the Bayh-Dole Act come into play.

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Stanford v. Roche, 563 U.S. at ____ (slip op. at 8-9, 10, 12). Thus, the Supreme Court has established a bright line rule that "[t]he Bayh-Dole Act does not automatically vest title to federally funded inventions in federal contractors or authorize contractors to unilaterally take title to such inventions." *Id.* at ____ (slip. op. at Syllabus p. 2). The corollary is that title to a federally funded invention also does not automatically vest in the federal government.

The *Stanford v. Roche* decision may seem obvious and simply a restatement of 200 years of established patent law that stands for the fundamental premise that an employee inventor has ownership rights in his invention. However, for federal contractors and grantees, the Supreme Court decision is less obvious. One implication of this decision for federal government contractors and grantees is explained in the dissent to the *Stanford v. Roche* decision. According to the dissent, the Supreme Court has effectively eliminated the Bayh-Dole Act three-tier system for patent rights ownership where (1) the federal contractor or grantee; (2) barring that, the federal government; and (3) barring that, the employee inventor obtains rights in federally funded inventions. See *id.* at _____ (slip op. at Dissent p. 1-3) (Breyer, J. dissenting) (citing 35 U.S.C. §§ 202-203). The majority held that the Bayh-Dole Act does not establish such a three-tier system. Thus, the *Stanford v. Roche* decision settles an ambiguity in the law, establishing that the employee inventor has priority in ownership rights for a federally funded invention under the Bayh-Dole Act.

In light of the Stanford v. Roche decision, federal government contractors and grantees should take the following steps:

- Establish agreements with its employees that require each employee to make present assignments to the contractor or grantee for inventions made during his or her employment.
- Establish agreements with third parties, including consultants, that protect each party's rights in inventions developed during collaborative efforts consistent with the terms of the government contract.
- Recognize that, as a federal contractor or grantee, it may be in *breach of its federal contract or grant* if it fails to obtain: (1) an assignment (preferably a present assignment) of a federally funded invention from an employee; or (2) an agreement on rights in a federally funded invention from a third-party collaborating organization or consultant.
- Recognize that the *federal government may propose new rulemaking* in connection with patent rights that may include regulations that require contractors to obtain (and perhaps certify that they have obtained) the assignments from employees, as well as agreements with collaborating organizations and consultants discussed above.
- Understand that patent rights are not implemented in federal contracts and grants uniformly across the federal agencies and, as such, a federal government contractor or grantee should *carefully review its rights and responsibilities* under the patent rights clauses in each of its contracts or grants.
- Recognize that under certain circumstances, a federal contractor or grantee should *negotiate patent rights with the federal* government.
- Recognize that, pursuant to the definition of "subject invention" in a federal government grant or contract, the *federal* government may obtain rights in inventions conceived at private expense, but first reduced to practice using federal funding, or alternatively, conceived using federal funding, but first reduced to practice at private expense.
- Recognize that, as a federal government contractor or grantee, it may need to review the federal government contract or grant, as well as agreements made in connection with the contract or grant, to determine rights to a federally funded invention.
- Recognize that, to determine rights to a federally funded invention, *third parties* acquiring patent rights from a federal government contractor or grantee may *need to review* the federal government contract or grant, as well as agreements made in connection with the contract or grant.
- While not specifically addressed by the Supreme Court, recognize that the precedent set in the Stanford v. Roche decision is likely to apply to large, for-profit companies, as well as to small businesses and nonprofit organizations that are performing

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federal government contracts or grants. See Exec. Order No. 12,591, para. 1(b)(4), 52 Fed. Reg. 13,414 (Apr. 10, 1987) (citing President's Memorandum to the Heads of the Executive Departments and Agencies, Government Patent Policy (Feb. 18, 1983)).

Please contact Christopher Rissetto, Partner and Leader of the Reed Smith Public Policy & Infrastructure Group; Louis DePaul, Partner in the Reed Smith Intellectual Property Group; or Stephanie Giese, Senior Associate in the Reed Smith Government Contracts & Grants Group, for more information regarding intellectual property rights under federal government contracts and grants.

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