

## WSGR ALERT

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## U.S. SUPREME COURT HOLDS THAT BAYH-DOLE ACT DOES NOT AUTOMATICALLY VEST TITLE IN PATENTS TO GOVERNMENT CONTRACTORS FROM INVENTORS WORKING FOR THE CONTRACTORS

On Monday, June 6, 2011, the United States Supreme Court issued its decision in *Board of Trustees of the Leland Stanford Junior Univ. v. Roche Molecular Systems, Inc.* (*Stanford v. Roche*). In a majority decision<sup>1</sup> authored by Chief Justice John Roberts, the Supreme Court upheld the Federal Circuit's decision that the Bayh-Dole Act does not automatically vest title to federally funded inventions in federal contractors, such as universities conducting NIH-funded research. Although this decision prevents the Bayh-Dole Act from acting as a safety net for universities without appropriate employment agreements, careful attention to the language of invention assignment contracts will serve to preserve rights to university inventions. As a consequence, the decision will not normally impact the ability of universities to translate the results of research to a commercial setting.

### Bayh-Dole Act Overview

Passed in 1980, the Bayh-Dole Act<sup>2</sup> seeks to "ensure that the Government obtains sufficient rights in federally supported inventions." To achieve this, the act provides that rights to federally funded "subject invention[s]" are allocated between the federal government and federal contractors (defined as "any person, small business firm, or nonprofit organization that is a party to a funding agreement"<sup>3</sup>). Under the act, 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."<sup>4</sup> Contractors can "elect to retain title to any subject invention," but to do so they must fulfill several statutory obligations. In many cases, the contractor is a university that performs grant-funded research. In the case under discussion, the Bayh-Dole Act was important because a lower court had held that Stanford's employment agreement had not transferred title in a patent to the university.

### Background

The technology involved in the patents at issue is a polymerase chain reaction (PCR) test for human immunodeficiency virus (HIV). In the late 1980s, Cetus and Stanford began to collaborate to test new drug efficacy. A research scientist at Stanford (Mark Holodniy) joined Stanford's Department of Infectious Diseases. Upon joining the department, Holodniy signed a contract with Stanford stating that he would "agree to assign" his "right, title and interest in" inventions resulting from his employment. Holodniy, who was unfamiliar with PCR at that time, went to Cetus to learn PCR techniques and research PCR quantification of patient HIV levels from blood samples. Cetus, a pioneer in the development of PCR, employed scientists who won the Nobel Prize for their discovery and

was a cutting-edge expert in the field at the time. As a condition of utilizing Cetus' expertise, Holodniy signed a confidentiality agreement that stated that he "will and do[es] hereby assign" his "right, title and interest in each of the ideas, inventions and improvements" made "as a consequence of access" to Cetus.

During his nine months at Cetus, Holodniy, working with Cetus employees, developed a PCR-based procedure for measuring blood HIV levels. Holodniy then returned to Stanford, where he and other Stanford employees tested the techniques he developed at Cetus. Stanford filed several patent applications on the technology and then obtained assignments—which Stanford believed to be merely confirmatory of earlier assignments—from the employees, including Holodniy. Some of this research was funded by the National Institutes of Health (NIH) and Stanford met its statutory obligations under the Bayh-Dole Act to retain title to the patents. In 1991, Roche Molecular Systems acquired Cetus' PCR assets, including the contract signed by Holodniy. Roche commercialized the technology as HIV test kits, which are currently in worldwide use.

In 2005, Stanford filed a patent infringement suit against Roche. Roche responded by asserting that Stanford lacked standing to sue because Roche was a co-owner of the

<sup>1</sup> Justice Sonia Sotomayor filed a concurring opinion. Justice Stephen Breyer filed a dissenting opinion, in which Justice Ruth Bader Ginsburg joined.

<sup>2</sup> 35 U.S.C. §200.

<sup>3</sup> §§201(e), (c), 202(a).

<sup>4</sup> §201(e).

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patents covering the HIV test kits due to Holodniy's assignment to Cetus. Stanford argued that Holodniy had no rights to assign because part of the research conducted by the university was federally funded, and that their rights to the invention were assured by the Bayh-Dole Act.

### The Supreme Court Decision

Stanford argued that the Bayh-Dole Act should automatically transfer title to the university, but the Supreme Court held in favor of Roche. In denying the validity of Stanford's position, the Court focused on the preclusive effect of the Bayh-Dole Act on the inventor's interests in the invention. The Court first noted the primacy of the inventor's ownership of his inventions, and recited several provisions of the Patent Act requiring that the inventor has initial ownership of a patent. Additionally, the Court noted precedents that confirmed the general rule that rights in inventions belong to the inventor, who may assign those rights to others. The Court also noted that "mere employment" is insufficient to convey title to an invention from an employee to an employer without "an agreement to the contrary." At the district court and Federal Circuit levels, Stanford argued that the "agree to assign" language was appropriate because the inventions had not been invented at the time the original contract with Holodniy was signed. However, both lower courts found that, because the Stanford employment agreement was written only in "future tense" (i.e., "I agree to assign...") as opposed to present tense (i.e., "I do hereby assign..."), Cetus obtained the first assignment of the patent rights. Thus, the Supreme Court decision effectively affirmed these findings.

The Court declined to adopt Stanford's interpretation of the Bayh-Dole Act to usurp these previous rulings. As the Court noted, the act does not expressly divest inventors of their rights, nor does it expressly vest those rights in contractors. The Court held that the Bayh-Dole Act's definition of a "subject invention" as "any invention of the contractor conceived or first actually reduced to practice

in the performance of work under a funding agreement" should not be interpreted to mean that any inventions made by an employee of a contractor were property of the contractor. Instead, the Court held that this language only applied to inventions owned by the contractor, such as via a valid assignment contract.

### Observations on the Holding

The Supreme Court's interpretation of the Bayh-Dole Act prevents organizations receiving government research funding from using the act as a safe harbor to guard their rights to employees' inventions. The decision in *Stanford v. Roche* is also instructive for employers seeking to secure rights in their employees' inventions. Employers should refrain from using mere "promise" language, such as "agrees to assign," in invention assignment or employee contracts. Instead, definite language such as "hereby does assign" in addition to the "promise" language in such contracts is advisable. In most cases, employment agreements are drafted with the "hereby does assign" language.

In most cases, this decision will be of little impact. It would apply only when (a) a university or other employer has only the "future" assignment language in an employment agreement, and (b) the researcher signs a contrary agreement *before* assigning the patent rights to the university. In light of this case, it is worthwhile for investors and companies to perform diligence on this issue when an important technology is in-licensed, and to review the assignment language in their employee and consultant agreements.

### Further Guidance

For further guidance on how to evaluate your patent portfolio, assignment contracts, and employee contracts in light of this decision and its potential implications, please contact Vern Norviel, Suzanne Bell, or another attorney in the intellectual property or technology transactions practices at Wilson Sonsini Goodrich & Rosati.



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