

Are Bayh-Dole's Best Days Over?

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Law360, New York (March 23, 2011) -- The parties in *Stanford v. Roche* present the Supreme Court with vastly different visions of the scope of the Bayh-Dole Act. *Stanford* would have the court rule that the act has broad scope, sweeping within its ambit any invention that has been touched by federal funding.



Roche construes the act more narrowly, so narrowly the act would be irrelevant to its contest with *Stanford* over patents that arose, at least in part, from federally funded research.

The court's decision will not only decide when issues of ownership are controlled by the act, but may also determine whether the act will be central to the partnership between industry and nonprofit research institutions as it has been for the past several decades.

Bayh-Dole was enacted in 1980 to allow research institutions to own patents covering certain "subject inventions" that had been created with federal funding. Previously, the U.S. government took title to a majority of those patents, but almost universally failed to commercialize them.

Allowing research institutions, referred to as "contractors" under the act, to own and largely control those patents has resulted in a dramatic increase in commercialization of federally funded research, as was expected when the law was passed.

Under Section 202 of 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 [federal] funding agreement." The contractor is required to report any subject invention to the fund granting agency, such as the National Institutes of Health (NIH), but may "elect to retain title to any subject invention."

In exchange for title, the act places a variety of requirements on the nonprofit contractor, including: filing a patent application; attempting to commercialize the inventions, with certain preferences to small business firms and manufacturers in the U.S.; limiting assignment of the patents; sharing royalties with the inventors; and granting a nonexclusive license to the government.

The government may also exercise "march-in rights" to license or force the contractor to license the rights under certain circumstances and may even take title if the contractor fails to live up to its obligations or does not elect to take title initially.

The dispute between Stanford University and Roche Molecular Systems Inc. grew out of conflicting

agreements in which a Stanford researcher-inventor ostensibly assigned the same patent rights to both Stanford and a Roche predecessor, Cetus.

In the late 1980s researchers at Stanford were attempting to develop an assay to measure levels of HIV in a patient to determine the effectiveness of various anti-viral treatments. Some of that research was accomplished using funding from the NIH. The researchers had signed Stanford's standard patent agreement where they "agree[d] to assign" to Stanford rights to patents resulting from their research.

One of the Stanford researchers visited Cetus over a nine-month period in 1989 to gain knowledge about polymerase chain reaction (PCR) techniques Cetus had invented that could be useful in developing the HIV assay. Prior to visiting Cetus and learning about PCR, the researcher signed an agreement in which he "hereby assigns to Cetus my right" to any invention that resulted from his access to Cetus.

Stanford eventually filed patent applications on use of an assay for determining the amount of HIV present in a patient to determine the effectiveness of HIV therapies. The patents issuing from those applications indicate that they were supported by government funding and that the inventors include the researcher who had entered into the agreement with Cetus.

Cetus/Roche developed and began selling an assay kit for monitoring HIV levels. After a period of negotiation, Stanford filed suit against Roche alleging that use of the Roche assay infringed the Stanford patents. Roche's response included the defense that Roche should have been an owner of the relevant patents through the agreement between Cetus and one of the inventors, and therefore could not be liable for infringement.

The district court held that the agreement which purported to assign rights to Cetus was ineffective because such an assignment would be inconsistent with Bayh-Dole, which the court believed requires title be held solely by Stanford.

The Court of Appeals for the Federal Circuit reversed, finding that contract principles vested title with Cetus/Roche because Cetus had received a present assignment of the researcher's rights through the "hereby assign" language. The agreement with Stanford, although earlier in time, vested only equitable title in Stanford because it was only "an agreement to assign," not an actual assignment transferring legal title.

The Federal Circuit then held that the act did not override the relevant contract law because it only applied to patents for which the contractor would have title under contract law. Roche was effectively a co-owner and the suit, therefore, had to be dismissed because Stanford lacked standing to bring the suit without a co-owner. The Supreme Court granted certiorari to determine whether the act should take precedence over the agreements of an inventor.

Under Stanford's view of the act, patents arising from federally funded research are automatically covered by the act's provisions that permit the research institution to elect title. Under this interpretation, neither the inventors nor the institution can enter into agreements that would circumvent the procedures in the act.

To do so would call into question ownership of patents on subject inventions, making it more difficult to license those patents, thereby undercutting the primary purpose of the act. Allowing inventors or institutions to “contract around” Bayh-Dole would also lead to the government losing many of its other rights, including the ability to direct commercialization to small businesses or U.S. manufacturers, the government’s own license and march-in rights, as well as the right to ensure that the fruits of federal funding are diligently commercialized for the public benefit.

Roche counters that under the act, the institution is only able to elect to “retain” title, meaning that the act only applies to patents for which it would otherwise have ownership under applicable employment or contract law. If the act were to trump other areas of law, it would necessarily impinge on the rights of entities other than the funded institution and its inventors, which Roche asserts was not Congress’s intent and could also raise constitutional issues.

Roche foresees little chance that institutions or their inventors will be able to or even attempt to contract around the act. For instance, the government could require institutions to obtain ownership from their inventors by avoiding the problematic “agree to assign” language, minimizing the chance for circumvention of the act, and, in any event, every institution has a strong incentive to preserve the government’s rights, lest the institution risk losing its most important research funding source.

At oral argument before the Supreme Court on Feb. 28, 2011, some of the justices seemed to be searching for a way to limit the case to its unusual facts, without having to address the breadth of the act. That would appear to be an unlikely result, given that most of the facts have already been set in the record that the breadth of the Bayh-Dole Act is the only issue for which certiorari was granted, and that at this stage, Stanford’s success or failure relies entirely on whether the act is applicable.

Much of the argument, particularly the questioning of the solicitor general, dealt with the potential loss of the government’s rights if the contracts of inventors could effectively avoid the restrictions of the act, thereby undercutting the value to the government and the public of the research they fund.

Many of those rights, however, are rarely applied; the government has never used its march-in rights and may waive other rights and restrictions under the act. If the Supreme Court finds for Stanford based on the rationale of preserving the government’s rights, it may correctly have interpreted Congress’s intent, but would be side-stepping other important results of the act supporting Stanford’s position, namely the relationship between institutions and their licensees.

If the court were to find for Roche, particularly with a broadly worded decision, it could have significant impact on the future licenses involving research institutions. Most universities treat the requirements of Bayh-Dole as sacrosanct and apply them even in licenses for inventions not funded by the government.

The importance of Bayh-Dole to research institutions is largely because the federal government is the major source of research funding and Bayh-Dole has been an important driver of their ability to reap benefits from their research, but also because the Bayh-Dole requirements are aligned with their mission to benefit the public and their obligations under federally funded grants.

Prospective licensees find many of the Bayh-Dole-driven restrictions to be foreign to the for-profit

world, but generally agree to them because of the assumed breadth of the act. A research institution's arguments about what needs to be included in a license are far more persuasive when they can point to the act and argue that without compliance, not only the institution, but also the licensee can lose its rights in the unlikely event that the government decides to use its march-in rights or takes ownership to the licensed patents.

For-profit companies knowledgeable about the strings that come with licensing inventions from government funded research often minimize the impact of Bayh-Dole on their businesses by restricting research institutions from comingling government funding in projects the company funds.

If *Stanford v. Roche* creates other avenues to avoid the restrictions of Bayh-Dole, such as by entering into contracts that vest title with an entity other than the government funded institution, prospective licensees may push for deal structures that create tension with the institution's perceived or actual obligations under their grants, the act or their mission to benefit the public. That could lead to greater risks for those institutions if they proceed with such deal structures, or fewer deals if institutions decide not to bear those risks.

To date, there is little case law construing Bayh-Dole, and that fact may also be a cause for what appeared to be a struggle on the part of the justices during the oral argument to construe some of its minimally defined provisions. The parties used other passages of the act to buttress their arguments about the meaning of the language that is central to their dispute, but those other passages themselves have little or no case law from which to ground their meaning.

The paucity of case law on the act is one of the reasons that a decision in *Stanford v. Roche* is eagerly anticipated by research institutions and their licensees.

Even if the majority attempts to draft a narrow opinion, the lack of other case law means the decision will undoubtedly be cited in any future dispute over the act, including disputes that do not relate to ownership. Whether *Stanford* or *Roche* prevails, the case will likely impact the work under every federally funded grant and the billions of dollars to the U.S. economy that result from scientific research, whether public, private or, as in *Stanford v. Roche*, through a combination of the two.

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