

U.S. Supreme Court Reaffirms Importance of Well-Crafted Agreements to Clarify Title to Patented Inventions Among Businesses, Universities, Researchers, and the Government

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What happens when a contract, the Patent Act, and the Bayh-Dole Act purport to give ownership in the same patent to the government, a university, and a university researcher, all at the same time? The US Supreme Court recently answered this question in *Stanford Univ. v Roche Molecular Sys., Inc.*, 131 S. Ct. 2188 (2011). The Court's opinion highlights the importance of protecting and delineating IP ownership rights in federally funded research projects by using well-drafted and unambiguous ownership and assignment agreements. The Court's decision also stokes the policy debate between commercial protection of IP on the one hand, and on the other hand sharing publicly-funded inventions for the public good.

The Bayh-Dole Act

Congress passed the Act to "promote the utilization of inventions arising from federally supported research," "promote collaboration between commercial concerns and non-profit organizations, including universities," and "ensure that the Government obtains sufficient rights in federally supported inventions." The Act allows a federal contractor receiving federal funds that result in an invention to elect to retain title to the invention by disclosing it to the federal agency that provided the funding, making a written election to the agency that the contractor wishes to retain title, and by filing a timely patent application. The federal agency that provided the funding receives a license to practice the invention, and may gain right to grant a license to a third party if the contractor does not take "effective steps to achieve practical application." Failure by a federal contractor to properly reserve its ownership rights to a federally funded invention under the Act's procedures may give the government ownership rights. It also provides the government with discretion to consider requests by contractors to retain ownership rights.

The Basic Facts of the High Court's Stanford Opinion

A research company named Cetus developed a Nobel Prize winning technique called polymerase chain reaction (PCR), which was an important part of its efforts to develop methods to quantify blood-borne levels of human immunodeficiency virus (HIV), which causes AIDS. Cetus then partnered with Stanford University's Department of Infectious Diseases to test AIDS drugs. Dr. Mark Holodniy was a research fellow at Stanford who worked on the project. Holodniy signed an agreement wherein he "agreed to assign" to Stanford rights to all inventions from his employment. While employed by Stanford, Holodniy spent nine months at Cetus pursuant to its partnership with Stanford, working with Cetus employees, and "devised a PCR-based procedure for calculating the amount of HIV in a patient's blood." Holodniy signed an agreement with Cetus wherein he said he "will assign and does hereby assign to" Cetus rights in all inventions made "as a consequence of his access to Cetus." Holodniy then returned to Stanford, and with the help of other Stanford researchers, refined the HIV measurement process. Stanford's research for this process was funded by the National Institute of Health. Stanford secured three patents to the process. Holodniy and the other researchers filed

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the patent applications, but assigned their rights in the patents to Stanford. Stanford properly secured ownership rights vis-à-vis the National Institute of Health pursuant to the Bayh-Dole Act procedures summarized above.

Roche Molecular Systems purchased Cetus' PCR-related assets, including the rights obtained in the assignment agreement between Cetus and Holodniy. Roche conducted clinical trials on the Cetus method, commercialized the procedure, and sold HIV test kits used in hospitals and AIDS clinics around the world. Stanford sued Roche arguing its HIV kits infringed Stanford's patents.

The Arguments

Roche argued that it was a co-owner of the HIV quantification procedure patented by Stanford based on Holodniy's assignment of rights agreement with Cetus. Thus, Stanford lacked standing to sue it for patent infringement.

Stanford argued that Holodniy had no rights to assign to Cetus because Stanford had superior rights in the invention under the Bayh-Dole Act. In other words, Stanford argued that the Act re-orders the normal priority of patent ownership rights to prioritize government-funded inventors over third parties, thus rendering Cetus' assignment-of-invention agreement with Holodniy void *ab initio*. Put yet another way, Stanford argued that the Act could deprive private third parties of patent ownership rights achieved pursuant to established operation of contract and patent law in favor of government-funded patent owners.

The Supreme Court's Response

In a 7-2 majority opinion, the Court sided with Roche. Pursuant to the Court, the Bayh-Dole Act does not "set aside two centuries of patent law" by altering the normal priority of patent ownership rights; it does not divest inventors of their rights to inventions, even if publicly funded. Congress does by express statute divest certain inventors of patent rights in contracts with certain government agencies (e.g., Atomic Energy Commission, NASA), but did not do so in the Bayh-Dole Act. And the Court would not infer such an interpretation into the Act. So, the Court affirmed the validity of the general operation of contract law, property law, and patent ownership rights with the Bayh-Dole Act as follows:

- The general rule under Article 1, section 8, clause 8 of the U.S. Constitution, and the Patent Act, is that rights in an invention belong to the inventor.
- An inventor can assign his rights in an invention to a third party. But the third party must be able to trace its rights back to the inventor.
- "[U]nless there is an agreement to the contrary, an employer does not have rights in an invention 'which is the original conception of the employee alone.'"
- An inventor "must expressly grant his rights in an invention to his employer if the employer is to obtain those rights."
- The Bayh-Dole Act does not make all inventions of employees property of their employers if their employer receives federal funding, thus becoming a federal contractor. In other words, "a contractor's invention — an 'invention of the contractor' [under the Act] — does not automatically include inventions made by the contractor's

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employees.”

- “The Bayh-Dole Act does not confer title to federally funded inventions on contractors or authorize contractors to unilaterally take title to those inventions; it simply assures contractors that they may keep title to whatever it is they already have.”
- “Only when an invention belongs to the contractor does the Bayh-Dole Act come into play.”
- “[U]niversities typically enter into agreements with their employees requiring the assignment to the university of rights in inventions. With an effective assignment, those inventions – if federally funded – become ‘subject inventions’ under the Act”
- The dissent interpreted the Act to automatically vest title to an employee’s invention to his employer (the federal contractor) without an assignment-of-invention agreement, thus depriving Holodniy of any right to assign to Cetas (which was purchased by Roche), thus making Stanford the winner. The dissent opined that because the public paid to produce the invention, the public interest should receive its benefit over a commercial interest, and that this policy is reflected in other Acts of Congress.

Miller Canfield’s Take Aways

- The federally funded University contractor must obtain rights to its employees’ inventions with valid assignment-of-rights agreements before the University can exercise its options under the Bayh-Dole Act to take ownership in inventions created with federal funding.
- The majority opinion is based on a Federal Circuit decision that prioritizes assignment-of-rights agreements with language stating the employee “will and [does] hereby assign” invention rights to his employer, over agreements with language that the employee “agrees to assign” invention rights. The latter language (contained in the Stanford agreement with Holodniy) only conveys a future right requiring a further act of assignment, while the former language (contained in the Cetus agreement with Holodniy) captures ownership of an invention once it comes into existence.
- The Court did not analyze the assignment-of-invention agreements at issue because they were not raised in the lower court. Thus, there is not much guidance from the *Stanford* Court on the substance of the agreements, other than the importance of ensuring the assignment language clearly indicates a present transfer of ownership rights (even if the invention does not yet exist), rather than merely a conditional future grant. However, as the Court indicated, the issue of determining title to an invention will be governed by established contract principles.
- If your Company or University has employees working with contractors, ensure you have an assignment-of-inventions agreement with your employees, know whether the contractor has one with your employees, and consider executing a joint-development agreement with the contractor to avoid the issues posed by *Stanford*.
- The Court’s *Stanford* opinion reinforces the importance of making clear who owns the work product of a business or university’s R&D, and doing so with clear and unambiguous terms and agreements.

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Miller Canfield's Global IP team stands ready to help assess, quantify, and protect your valuable IP portfolio.

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