

Be careful with your agreements: Bayh-Dole Act does not automatically confer ownership of inventions from inventors to institutions receiving federal funds

Court holds Bayh-Dole Act simply assures that contractors may keep title to what they already have

The Supreme Court recently held in *Stanford v. Roche* that the Bayh-Dole Act (also known as the University and Small Business Patent Procedures Act of 1980, the "Act") does not confer title to federally funded inventions on contractors or authorize contractors to unilaterally take title to those inventions. Instead, the Act "simply assures contractors that they may keep title to whatever it is they already have." Therefore, the institution may **retain** its ownership provided it meets the remaining requirements of the Act only if it has an agreement with an inventor assigning his or her rights in a federally funded invention.

Upon joining Stanford University, Dr. Mark Holodniy agreed "to assign" to Stanford his "right, title and interest in" inventions resulting from his employment at Stanford. As part of this research, Dr. Holodniy's supervisor arranged for him to conduct research at Cetus, a research company developing methods for quantifying blood-borne levels of HIV. As a condition for gaining access to Cetus, Dr. Holodniy signed a second agreement by which he actually assigned to Cetus his "right, title and interest in each of the ideas, inventions and improvements" made "as a consequence of [his] access."

Dr. Holodniy conducted research at Cetus for the next nine months devising a procedure for calculating the amount of HIV in a patient's blood. Dr. Holodniy then returned to Stanford where he and other Stanford employees developed an HIV measurement technique. Stanford filed several patent applications related to the technique and obtained written assignments for the inventors, including from Dr. Holodniy.

Roche later acquired all of the rights of Cetus, including the rights to the assignment between Dr. Holodniy and Cetus. In 2005, Stanford filed a patent infringement suit against Roche contending that Roche's HIV test kits infringed Stanford's patents. Roche responded by asserting that it was a co-owner of the HIV quantification procedure based upon Dr. Holodniy's assignment to Cetus. Stanford countered that Dr. Holodniy had no rights to assign because his research was federally funded giving Stanford superior rights in the invention under the Bayh-Dole Act.

The Act allocates rights in federally funded "subject invention[s]" between the federal government and federal contractors. The Act defines "subject invention" as "any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement," and provides that contractors may "elect to retain title to any subject invention." As the National Institutes of Health (NIH) funded some of Stanford's research on the HIV measurement technique, the Bayh-Dole Act applied. In accordance with the requirements of the Act, Stanford notified NIH that it was electing to retain title to the invention and conferred on the government a license to use the patented procedure.

The District Court held that the Dr. Holodniy effectively assigned rights to Cetus, but because of the Bayh-Dole Act, Dr. Holodniy had no interest to assign when he signed that agreement. The Federal Circuit then reversed the District Court, holding that Roche did have an ownership interest in the patents-in-suit, and the Supreme Court granted *certiorari*.

In affirming the Federal Circuit, the Supreme Court held that "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."

The Supreme Court rejected Stanford's contention that the Act reorders the normal priority of rights in an invention when the invention is conceived or first reduced to practice with the support of federal funds. The Supreme Court



stated that no where does the Act expressly vest in contractors or anyone else title and nowhere in the Act are inventors expressly deprived of their interest in federally funded inventions.

The Supreme Court went on to state that only when an invention belongs to the contractor does the Act come into play. The Act serves to clarify the order of priority of rights between the federal government and a federal contractor in a federally funded invention that already belongs to the contractor. By using the word “retention” the Act assumes that the inventor had rights in the subject invention at some point, undermining the notion that the Act automatically vests title to federally funded inventions in federal contractors.

Finally, the Supreme Court noted that its construction of the Act reflects the common practice among parties operating under the Act, *i.e.*, contractors generally institute policies to obtain assignments from their employees. Universities 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, and the Act as a practical matter works pretty much the way Stanford says it should.

This decision emphasizes the importance of obtaining proper assignments of inventions from employees and contractors. Institutions cannot and should not rely upon the Act to vest ownership in inventions created using federal funds. Therefore, anyone that receives federal funds and is subject to the Act should review their assignments to ensure that the agreements effectively assign rights in any inventions, including, without limitation, those that are federally funded to the institution. Moreover, it is imperative that institutions ensure that their employees have not otherwise assigned their rights in an invention to a third party, especially those involved in shared research.

As a side note, the Federal Circuit in reaching its decision held that Dr. Holodniy’s agreement with Stanford constituted a mere promise to assign rights in the future, but that his agreement with Cetus actually assigned his rights in the invention to Cetus. While the Supreme Court did not address this issue, the applicable agreements with employees and contractors should themselves assign rights in the invention and not be a mere promise to assign in the future.

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