

Supreme Court Holds Bayh-Dole Act Does Not Automatically Vest Patent Rights in Federally Funded Inventions to Federal Contractors

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On June 6, 2011, the United States Supreme Court held that the University and Small Business Patent Procedures Act of 1980—also known as the Bayh-Dole Act—does not automatically vest federal contractors with the patent rights to federally funded inventions created by their employees. Under the Bayh-Dole Act, federal contractors may "elect to retain title" to "subject inventions"—in effect, inventions that are conceived or first actually reduced to practice with federal funds—in exchange for following certain procedural requirements. In *Stanford v. Roche*, No. 09-1159 (U.S. June 6, 2011), the Supreme Court affirmed the 2009 decision of the U.S. Court of Appeals for the Federal Circuit, which held that the Bayh-Dole Act did not give Stanford University superior property rights in a polymerase chain reaction (PCR) testing procedure created by one of its researchers, Dr. Mark Holodniy.

In 1985, Dr. Holodniy began developing a PCR testing procedure designed to quantify the amount of HIV in a person's bloodstream. The National Institutes of Health (NIH) partially funded Dr. Holodniy's research, placing the fruits of his research squarely within the scope of the Bayh-Dole Act. Dr. Holodniy also executed a Copyright and Patent Agreement (CPA) under which he "agree[d] to assign," but did not actually assign, his "right, title and interest in" inventions resulting from his employment to Stanford. Stanford secured three patents to Dr. Holodniy's HIV-measuring process.

While at Stanford, Dr. Holodniy also collaborated with Cetus, a small California research company also working on ways to quantify bloodborne HIV. As part of this collaboration, Dr. Holodniy signed a

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Visitor's Confidentiality Agreement (VCA) in which he both agreed to assign and actually assigned his intellectual property interests to Cetus.

Roche Molecular Systems eventually purchased Cetus's PCR-related assets, including the rights that Dr. Holodniy assigned to Cetus. When Roche commercialized the HIV measurement procedure that it acquired from Cetus, Stanford filed suit for patent infringement. Roche argued that it was a co-owner of the patented invention by virtue of Dr. Holodniy's VCA with Cetus, and that Stanford accordingly lacked standing to sue for infringement. Recognizing that its CPA lacked an actual assignment of rights, Stanford responded that the Bayh-Dole Act automatically vested Dr. Holodniy's property rights in the University, thus leaving him without anything to assign to Cetus and rendering the VCA an empty promise.

The Supreme Court rejected Stanford's argument. Relying on the centuries-old fundamental premise "that inventors have the right to patent their inventions[,]," the Court held that Congress did not "subtly set aside two centuries of patent law in a statutory definition." Slip op. at 6, 9. According to the Court, "unless 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.'" *Id.* at 7 (citations omitted). In support of its holding, the Supreme Court examined other Congressional statutes that expressly and unambiguously divest inventors of their rights. In contrast to these statutes, the Bayh-Dole Act merely allows federal contractors to "retain" title already owned by the contractor. 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." *Id.* at 12 (emphasis added).

The Supreme Court has now made it clear that the Bayh-Dole Act merely allocates rights in federally funded inventions between the Federal Government and federal contractors, and does not address or alter the rights of the individual employee who developed the invention. Accordingly, it is important now more than ever for contractors involved in federally-funded research and development projects to require their employees, consultants, and other appropriate individuals to execute assignments of their intellectual property rights in favor of the contractor.