

Bayh-Dole Act Does Not Automatically Give Universities Patent Rights

The United States Supreme Court recently decided the well-reported case of *Board of Trustees of The Leland Stanford Junior University v. Roche Molecular Systems, Inc.*, No. 09-1159 (U.S. Jun. 6, 2011). This case has implications for all research universities, including UAHuntsville, and deserves a close review.

The facts of *Stanford v. Roche* are complex. In general, a researcher at Cetus Corporation, a small California based research firm, won a Nobel Prize for a technique developed at the company that became an important part of a test used to quantify the levels of the HIV virus in a patient. In 1988, a collaboration began between Cetus and Stanford's Department of Infectious Diseases. At about this same time, Dr. Mark Holodniy joined the Stanford department as a research fellow. When he joined Stanford, Dr. Holodniy signed a patent agreement in which he "agreed to assign" to Stanford all his right, title and interest in inventions resulting from his Stanford employment. It was agreed that Dr. Holodniy would conduct some of his research at the Cetus facility. In order to gain access to the Cetus facility, Dr. Holodniy was required to sign an agreement stating that he "will assign and does hereby assign" to Cetus all his right, title, and interest in ideas, inventions, and improvements made as a result of his access to Cetus facilities. Stanford's portion of the collaborative research was federally funded, and the research proved productive. Stanford filed for and was granted three patents involving Dr. Holodniy's research. At some point during the collaborative research project, Roche Molecular Systems, Inc. acquired Cetus's interest in the subject technology. After clinical trials, Roche commercialized an HIV test kit that is in worldwide use today. The test kit utilized, at least to some extent, the subject technology.

Stanford sued Roche claiming that the HIV test kit infringed its three patents. Roche defended by saying that the agreement signed by Dr. Holodniy with Cetus gave it co-ownership of the technology and that, therefore, Stanford lacked standing to sue for patent infringement. Stanford countered by saying that, since the research was federally funded, the Bayh-Dole Act gave Stanford superior patent rights. The United States Supreme Court disagreed with Stanford and held that it lacked standing to claim patent infringement against Roche, affirming the earlier decision of the Court of Appeals for the Federal Circuit.

Stanford v. Roche raises at least three issues that are important to UAHuntsville. The first is "the drafting" issue. Obviously, the Court favored the language used by Cetus ("and does hereby assign") to the "prospective" language used by Stanford ("agrees to assign"). The Stanford language envisions an assignment to occur at some future point in time. The Cetus language, on the other hand, refers to an assignment occurring contemporaneously with the execution of the document. The Board of Trustees of The University of Alabama reacted to the *Stanford v. Roche* drafting issue when the case was decided by the Court of Appeals for the Federal Circuit. *Stanford v. Roche*, 583 F.3d 832 (Fed. Cir. 2009). Following the publication of the Federal Circuit's decision, the Board amended its patent policy to state that the policy was contractual in nature and that assignments of patent rights occurred *automatically* at the moment of creation of intellectual property. Plans are already underway to add the *Stanford v. Roche*

approved phrase “and does hereby assign” to all new patent agreements signed by newly hired faculty members at all three University of Alabama campuses.

The second issue raised by *Stanford v. Roche* relates to the scope of patent rights granted to universities by *The University and Small Business Patent Procedures Act of 1980*, 35 U.S.C. 200 (1980), commonly known as the Bayh-Dole Act. Stanford, and the United States in an *amicus* brief, contended that when an invention is made with the support of federal funds, the Bayh-Dole Act operates to immediately vest title in the inventor’s employer, the federal contractor. The Supreme Court rejected this view and noted that for over two centuries the basic idea in patent law is that “inventors have the right to patent their inventions.” *Stanford v. Roche*, at 6. The Court noted that in the past Congress has unambiguously divested inventors of their rights and stated that certain inventions become the property of the federal government. There is no such unambiguous language in the Bayh-Dole Act. Universities, including UAHuntsville, that want to take advantage of the Bayh-Dole Act must be careful to see that all of its provisions are carefully followed.

Stanford v. Roche’s third issue highlights the difficulty that can arise when faculty members sign agreements without full knowledge and understanding of the legal implications of such agreements. There is nothing in *Stanford v. Roche* indicating that Stanford’s faculty member, Dr. Holodniy, shared in Roche’s commercialization proceeds. The Bayh-Dole Act requires federally funded contractors to share the proceeds of a successfully commercialized invention with the employee-inventor. Stanford, as well as UAHuntsville, has a program in place that complies with this revenue-sharing Bayh-Dole Act requirement. Although the case does not expressly make the point, it appears that Dr. Holodniy may have signed the Cetus facility access and patent rights assignment document without realizing that it had the legal effect of divesting him, along with Stanford, of a share of the potential commercialization revenue from his inventions. One lesson of *Stanford v. Roche* is that academia needs to carefully address the issue of how to best protect the intellectual property rights of the institution, as well as those of its faculty members, when dealing with third party research sponsors and collaborators.