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Reducing Legal Risk to Bayh Dole Act Intellectual Property: Are Inventor Assignments to Third Parties Valid?

On February 28, 2011 the U.S. Supreme Court heard oral argument in a case that may significantly impact the intellectual property rights of small businesses and universities that work in close collaboration to develop new inventions. Under the Bayh Dole Act, 35 U.S.C. §§ 200-212, small businesses and nonprofit organizations may "elect to retain title" to subject inventions, which the statute defines as inventions "conceived or first actually reduced to practice" under a government-funded agreement. In Stanford v. Roche, the Supreme Court will decide whether the Bayh Dole Act eliminates or constrains the ability of an inventor to unilaterally assign a university or small business contractor's ownership rights to a third party. Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc. et al., No. 09-1159 (certiorari granted Nov. 1, 2010).

The *Stanford* Case

Cetus Corporation (Cetus) developed a scientific technique called polymerase chain reaction (PCR) in the mid-1980's. In 1989, a Stanford researcher named Dr. Mark Holodniy worked as a visitor for a brief period at Cetus's facilities where he first conceived of a commercial application of PCR to detect and quantify levels of HIV in patients' blood. After returning to Stanford, Dr. Holodniy and other researchers conducted federally funded clinical trials of the PCR application, which eventually resulted in Stanford being granted three related patents.

Meanwhile, multinational pharmaceutical company Roche acquired Cetus and commercialized the PCR application without entering into a license or paying royalties to the university. Since 1996, Roche has sold kits for quantifying HIV levels in blood to hospitals and clinics worldwide. In 2005, when Roche refused Stanford's demands that it enter into a license and pay royalties, Stanford sued Roche for patent infringement.

Roche claims ownership of Dr. Holodniy's PCR application based on a contract that Dr. Holodniy signed while working at Cetus's facilities in 1989. This contract contained an assignment provision granting Dr. Holodniy's inventor ownership rights to Cetus for inventions Dr. Holodniy conceived of while working as a visitor at Cetus's facilities. On appeal, the Federal Circuit held that a similar contract that Dr. Holodniy signed with Stanford did not compromise Cetus's rights under the 1989 contract because Dr. Holodniy had only agreed to assign his inventor ownership rights to Stanford in the future. Under the 1989 contract, Dr. Holodniy agreed to assign Cetus both his present and future rights.

In addition to addressing these contract interpretation issues, the Federal Circuit held that the Bayh Dole Act did not negatively impact the rights that Roche had obtained upon acquiring Cetus.

Before the Supreme Court, Stanford argued that its ownership rights to Dr. Holodniy's PCR application were not contingent upon it receiving an effective assignment from Dr. Holodniy because, under the Bayh Dole Act, inventor rights are subordinate to those of Stanford and the government. A team of Venable attorneys filed an amicus brief on behalf of our partner, former United States Senator Birch Bayh raising similar arguments to those of Stanford regarding the purpose and construction of the statute. According to these parties, the Federal Circuit's decision conflicts with the clear hierarchy of rights provided in the Bayh Dole Act.

Practitioner Tips

Regardless of how the Supreme Court decides, the *Stanford v. Roche* case has led many universities, small businesses, and nonprofit organizations that employ engineers, researchers, and scientists for federally funded projects to revisit their policies and practices for drafting, negotiating, and monitoring intellectual property assignment provisions. This includes assignment provisions that often are included in employment contracts and agreements with third parties like Cetus. Whether assignment provisions are drafted as a present assignment (e. g. "I hereby do assign…") as opposed to a mere promise to assign the employee-inventor's rights in the future (e. g. "I will assign or agree to assign") may impact the priority of rights between the employer and other third parties.

Finally, the Supreme Court's decision on whether the Bayh Dole Act effectively voids an employee-inventor's purported contractual assignment of intellectual property rights without the consent of the employer and government may significantly impact the rights of entities that benefit from the Bayh Dole Act, including universities, small businesses, and nonprofits. Accordingly, it is important for these organizations to monitor how

the Supreme Court ultimately decides this case.

If you are a small business, nonprofit, university, or other organization that would like to know more about how the Bayh Dole Act may impact intellectual property rights arising from government-funded grants and contracts, please contact the authors of this alert or any member of the **Government Contracts** practice group.

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