November 4, 2010

Supreme Court to Address University's Patent Ownership Rights Under Bayh-Dole Act

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This week the Supreme Court agreed to address important issues regarding the ownership of inventions arising out of federal grants to universities, non-profit organizations, and small businesses. For the first time, the Supreme Court will be called upon to interpret the Bayh-Dole Act, a federal statute regulating ownership of patents arising from federally funded research. The Supreme Court's decision could have a significant impact on ownership rights for innumerable inventions made with the assistance of federal funding, as well as the procedures and agreements that universities, non-profit organizations, and small businesses use to manage relationships with their researchers.

On November 1, 2010, the Supreme Court granted certiorari in *Board of Trustees of Leland Stanford Junior University v. Roche Molecular Systems, Inc.* No. 09-1159, to review a decision of the United States Court of Appeals for the Federal Circuit dismissing Stanford University's patent infringement claims against Roche Molecular Systems, Inc. The Federal Circuit held that Roche acquired co-ownership of the patents-in-suit through an assignment agreement from one of the inventors, despite the Bayh-Dole Act.

The Court granted review at the urging of Stanford and the federal government, both of which contended that the Federal Circuit's decision could create serious uncertainty about title to patents arising from federally funded research and frustrate Congress's efforts to foster scientific research and development through the Bayh-Dole Act. Specifically, the Court granted review on the following question: "[w]hether a federal contractor university's statutory right under the Bayh-Dole Act, 35 U.S.C. §§ 200-212, in inventions arising from federally funded research can be terminated unilaterally by an individual inventor through a separate agreement purporting to assign the inventor's rights to a third party."

CASE BACKGROUND

In 1980, Congress enacted the University and Small Business Patent Procedures Act of 1980, 35 U.S.C. § 200 *et seq.*, better known as the Bayh-Dole Act. Under the Bayh-Dole Act, universities, other non-profit organizations, and small businesses that receive federal research funding "may, within a reasonable time after disclosure [of the invention], elect to retain title to any subject invention," subject to limitations and conditions imposed by the statute. 35 U.S.C. § 202(a). Before passage of the Bayh-Dole Act, ownership rights in federally funded inventions were subject to various statutes and regulations that depended on the particular agency funding the research. Under many of those prior regimes, ownership in inventions vested in the federal government.

The invention at issue in the Stanford case is a method for evaluating the effectiveness of HIV treatments that was developed in the late 1980s and early 1990s by researchers at Stanford and a company named Cetus. Stanford was the named assignee of the patent-in-suit. Because Stanford received funding for the research from the National Institutes of Health, Stanford exercised its rights under the Bayh-Dole Act to retain title to the inventions.

Prior to undertaking the research that led to the patents-in-suit, one of the named inventors, Mark Holodniy, signed a Copyright and Patent Agreement ("Stanford Agreement") with Stanford in which he "agree[d] to assign" title in subject inventions to Stanford. *Bd. of Trs. of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 583 F.3d 832, 837, 841 (Fed. Cir. 2009). But Holodniy subsequently conducted research at Cetus's facilities and signed a Visitor's Confidentiality Agreement ("Cetus Agreement") stating that he "will assign and do[es] hereby assign to CETUS" title in subject inventions. *Id.* at 837, 842.

In 2005, Stanford sued Roche for patent infringement in the Northern District of California. Roche, which had acquired Cetus, asserted ownership as both a counterclaim and an affirmative defense. The district court granted Stanford summary judgment on the ownership issues.

THE FEDERAL CIRCUIT'S DECISION

The Federal Circuit reversed the district court and ordered Stanford's patent infringement claims dismissed based on Roche's ownership of the patents-in-suit.

The Federal Circuit began its analysis with the various agreements signed by Holodniy. It concluded that the language "agree to assign" in the Stanford Agreement "reflects a mere promise to assign rights in the future, not an immediate transfer of expectant interests." The Court therefore concluded that "Stanford did not immediately gain title to Holodniy's inventions as a result of the [Stanford Agreement], nor at the time the inventions were created." *Stanford*, 583 F.3d at 841-42. By contrast, the Court held that the "do hereby assign" language in the Cetus Agreement "effected a present assignment of Holodniy's future inventions to Cetus" and that Cetus therefore acquired title by operation of law at the time of invention. *Id.* at 842. According to the Federal Circuit, "because Cetus's legal title vested first, Holodniy no longer retained his rights, negating his subsequent assignment to Stanford during patent prosecution." *Id.*

The Federal Circuit next rejected the district court's conclusion that "the Bayh-Dole Act negated Holodniy's assignment to Cetus because it empowered Stanford to take complete title to the inventions." *Id.* at 844. Unless the government exercised its rights under the Bayh-Dole Act, the Court concluded, title to inventions made under federal contracts remains with the named inventors or their assignees, and the Bayh-Dole Act does not "void[] prior contractual transfer of rights." *Id.* The Federal Circuit interpreted the Bayh-Dole Act as regulating relationships between contractors and the government, not between contractors and the inventors who work for them. Thus, the Federal Circuit held that the statute permits contractors like Stanford to retain whatever rights they would otherwise have in an invention, but does not grant them a "right of second refusal" to patents after the government declines to exercise its rights. *Id.*

STANFORD'S CERTIORARI PETITION

On March 22, 2010, Stanford filed a petition for writ of certiorari in the Supreme Court. Stanford's petition contended that the Bayh-Dole Act trumps the contractual analysis undertaken by the Federal Circuit and gives the federal contractor the right to take title to federally funded inventions unless the government exercises its superior rights. Stanford urged that Supreme Court review was necessary because the Federal Circuit's decision would allow an inventor's unilateral actions to circumvent a contractor's Bayh-Dole rights, as well as the limitations and conditions the statute imposes on ownership of federally funded inventions. Stanford further emphasized that the decision clouded title to "countless inventions" made over the past 30 years and imposed onerous burdens on universities, non-profit organizations, and small businesses to investigate the contractual relationships of their researchers.

In its opposition to Stanford's petition, Roche argued that the Bayh-Dole Act did not alter the long-standing principle that an inventor owns his or her invention absent a valid assignment agreement, and instead only allowed the contractor to "retain[] the title it would otherwise have had." Roche also suggested that the case was not worthy of Supreme Court review because it involved a unique factual situation and raised only settled principles regarding interpretation of assignment provisions, not Stanford's or the government's rights under the Bayh-Dole Act.

On June 28, 2010, the Supreme Court called for the views of the Solicitor General. The government filed its brief on September 28, 2010, urging the Supreme Court to grant certiorari and reverse the Federal Circuit's decision for many of the reasons identified by Stanford. The government argued that the Federal Circuit's decision "calls into question the government's ability to manage federally funded inventions for the benefit of the public" because it "allows individual inventors to allocate the benefits of federally funded research to third parties through individual contract assignments, rather than to contractors and the public, as Congress intended."

The Supreme Court granted certiorari on November 1, 2010. Stanford's brief is due in mid-December, with Roche's brief due a month later. The Supreme Court has not yet scheduled the case for oral argument, but it likely will be heard in the spring, and a decision will be issued by the end of June 2011.

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