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Inside Stanford V. Roche

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Law360, New York (June 22, 2011) -- The U.S. Supreme Court's June 6, 2011, decision in *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems Inc.* addressed whether a research institution's use of federal funding, thereby implicating the Bayh-Dole Act, displaces the traditional U.S. patent law principle providing that ownership vests in the inventor.

Facts

In the early 1980s, a small company called Cetus developed methods to quantify blood-borne HIV levels known as polymerase chain reaction (PCR). In 1988, Cetus contracted with Stanford University's Department of Infectious Diseases to test the efficacy of new AIDS drugs. Shortly thereafter, Dr. Mark Holodniy joined Stanford's Department of Infectious Diseases. Dr. Holodniy's research at Stanford led him to work on-site at Cetus to learn more about its proprietary PCR techniques.

While at Cetus, Dr. Holodniy developed a PCR-based procedure to calculate the amount of HIV in a patient's blood. Upon returning to Stanford, Dr. Holodniy and other Stanford employees tested the procedure. Ultimately, three patents were issued to Stanford, which each captured various refinements of Dr. Holodniy's methods.

On joining Stanford, Dr. Holodniy signed a Copyright and Patent Agreement (CPA), under which he "agree[d] to assign" to Stanford his "right, title and interest in" inventions resulting from his employment at the University.[1] After joining Stanford, and in conjunction with his work at Cetus, Dr. Holodniy signed a Visitor's Confidentiality Agreement (VCA), stating that he "will assign and do[es] hereby assign" to Cetus his "right, title and interest in each of the ideas, inventions and improvements" made "as a consequence of [his] access" to Cetus.[2]

In 1991, Roche Molecular Systems acquired Cetus's PCR-related assets, including the VCA executed by Dr. Holodniy. Roche commercialized the procedure of quantifying HIV method developed at Cetus.

Dr. Holodniy's work at Stanford was funded, in part, by the National Institutes of Health (NIH). Stanford's receipt of federal funding implicates the University and Small Business Patent Procedures Act of 1980, commonly known as the "Bayh-Dole Act."

Among other things, the Bayh-Dole Act provides that a federal contractor — as between the federal contractor and the federal government — may elect to retain title to inventions conceived or reduced to practice by the contractor and funded, in whole or in part, by federal money.[3] If the federal contractor makes this election, and complies with certain procedural mechanisms, then the contractor receives title to the patented invention and the funding agency receives a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention.[4]

In 2005, Stanford University filed suit against Roche, asserting that Roche's HIV test kits

infringed the three patents in question. Roche responded by asserting that it was a co-owner of the patents and, as a result, Stanford lacked standing to sue Roche for patent infringement. Unwinding the various relationships, all parties proceeded on the assumption that Roche stood in the shoes of Cetus, and therefore received whatever rights Cetus held in the patents. The case presented the question of whether Cetus received any rights in the patents as a result of the VCA executed by Dr. Holodniy when he began working at Cetus.

Stanford argued that, because it had received NIH funding, the Bayh-Dole Act's invention assignment provisions trumped the express invention assignment clause of the VCA. In essence, Stanford claimed that the Bayh-Dole Act operated to assign all patent rights to Stanford, leaving Dr. Holodniy with no patent ownership interests that he could have assigned to Cetus, and thus Cetus had received no rights that it could sell to Roche.

The District Court agreed with Stanford, concluding that the Bayh-Dole Act "provides that the individual inventor may obtain title" to a federally funded invention "only after the government and the contracting party have declined to do so."^[5] The Federal Circuit reversed, holding that the Bayh-Dole Act "does not automatically void ab initio the inventors' rights in government-funded inventions" and that the "statutory scheme did not automatically void the patent rights that Cetus received from Holodniy,"^[6] ultimately remanding for dismissal of Stanford's patent infringement claim.^[7]

The Supreme Court's Holding and its Opinions

In a 7-2 opinion written by Chief Justice John Roberts, the Supreme Court affirmed the Federal Circuit, holding that, even considering the Bayh-Dole Act, Roche possessed an ownership interest in the three patents;^[8] the Bayh-Dole Act does not automatically vest title to federally funded inventions in federal contractors or authorize contractors to unilaterally take title to such inventions.^[9]

The court first reiterated the long-standing and basic principle that under United States patent law, ownership vests in the inventor unless there is an express agreement to the contrary.^[10] Thus, as inventor of the three patented inventions, ownership would ordinarily vest in Dr. Holodniy.

The court continued, however, that there is a similarly long-standing and basic principle that an inventor may freely assign his or her rights in an invention to his or her employer. The employer does not automatically receive ownership of the patent, but the employee may choose to assign his or her rights to the employer.^[11] Thus, as the express assignee of Dr. Holodniy's right, title and interest to any ideas, inventions and improvements made "as a consequence of [his] access" to Cetus, Cetus validly received rights to the three patents at issue.

The court found three reasons to reject Stanford's argument that the Bayh-Dole Act displaces this traditional regime. First, the court contrasted the dearth of language in the Bayh-Dole Act with respect to inventors' rights vis-à-vis contractors' rights with several other federal statutes that do expressly deprive inventors of their ownership rights.^[12] Second, the court construed several specific sections of the Bayh-Dole Act discussing contractors' rights vis-à-vis the federal government, stating that those sections would be superfluous if it were assumed that the contractor — not the inventor — was the original vestee of ownership rights.^[13]

And third, the court advanced an argument of public policy, noting that under Stanford's construction of the statute, if an inventor conceived of an invention prior to employment with a contractor, but the contractor received \$1 of federal funding in the reduction to practice of that invention, the contractor would automatically receive ownership of the invention.[14] Noting the widespread and common practice of employers to obtain assignment agreements from their employees, the court stated that under its interpretation and with an effective assignment, "the statute as a practical matter works pretty much the way Stanford says it should."[15]

Justice Stephen Breyer, joined by Justice Ruth Bader Ginsberg, dissented. He noted that Congress enacted the Bayh-Dole Act "against a background norm that often, but not always, denies individual inventors patent rights growing out of research for which the public has already paid." [16] This philosophy is undoubtedly familiar to federal government contractors, who regularly work with Federal Acquisition Regulation and Defense Federal Acquisition Regulation Supplement data rights clauses, which provide that the federal government does not pay for the same work twice (first via federal funding, and then again by license).

He also highlighted a point which, though mentioned only briefly in the majority opinion, was pivotal to its decision: the interplay between the VCA executed between Dr. Holodniy and Cetus, and the CPA executed between Dr. Holodniy and Stanford. Roche had asserted its status as a co-owner of the patents in question, indicating its belief that Stanford similarly possessed ownership rights to the patents by virtue of the executed CPA. The Federal Circuit, noted, however, that "Holodniy's initial agreement with Stanford in the [CPA] constituted a mere promise to assign rights in the future, unlike Holodniy's agreement with Cetus in the [VCA], which itself assigned Holodniy's rights in the invention to Cetus." [17]

The court elected not to review the Federal Circuit's interpretation of the relevant assignment agreements as it was not an issue on which it granted certiorari. [18] As Justice Breyer notes, however, the court's result occurs only because it assumes the grant to Stanford in the CPA is a future grant. [19] Dr. Holodniy executed the CPA with Stanford first-in-time. If it had been a present grant of all of Dr. Holodniy's right, title and interest to the inventions, under the Federal Circuit's existing case law, both Stanford and Cetus would have received equitable rights to the patents. As between the two claims in equity, because Stanford's came first, Dr. Holodniy's subsequent assignment of rights to Cetus would have been functionally useless.

In other words, by the time he purportedly assigned any rights to Cetus, he would have had no rights left to assign. Stepping into the shoes of Cetus, Roche would have received no ownership rights in the patents at issue. After the Federal Circuit's 1991 opinion in *FilmTec Corp. v. Allied-Signal Inc.*, [20] however, Cetus would have had the superior claim. [21] And, as Justice Breyer notes, the difference in language between the two assignment clauses was not substantial. Accordingly, he would have remanded the case to the Federal Circuit for further briefing on the issue. [22]

Justice Sonia Sotomayor's concurrence shared Justice Breyer's concerns regarding the specific assignment language used in both the CPA and the VCA in light of *FilmTec*, but, because Stanford had failed to challenge the Federal Circuit's decision on those grounds, she agreed that the appropriate disposition was to affirm. [23]

Conclusion

The facts presented by this case illustrate a typical research collaboration between a private university, a small research-oriented company and the federal government. The court's decision provides useful clarity to the ownership of patented inventions developed in this environment and turns the analysis of ownership into a two-step process: 1) Determine whether the inventor has assigned rights in the invention at issue to his or her federal contractor employer. This question would be answered by reference to any invention assignment agreements, or lack thereof, between the employee and the federal contractor. 2) Determine whether the invention constitutes a "subject invention" for purposes of the Bayh-Dole Act, thereby entitling the federal government to receive ownership or license rights.

Further, in light of the court's adoption of the Federal Circuit's construction of the two assignment agreements, this case serves, yet again, to remind practitioners of the importance of using present grant language in all employee invention assignment agreements. A promise to assign in the future, as was the case for Stanford here, can have significant and unintended consequences.

With that said, if both the CPA and the VCA had included present grant language, both Stanford and Cetus could have assumed that it owned the patents, free and clear of any other parties. It is not difficult to imagine similar litigation ensuing that focuses on construction of similar assignment agreements. It may be advisable to specifically negotiate patent ownership in these types of collaborative research settings.

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[1] Bd of Tr. of the Leland Stanford Junior Univ. v. Roche Molecular Sys. Inc., 563 U.S. ____ (2011), slip op. at 2.

[2] Id.

[3] 35 U.S.C. § 202(c)(4).

[4] Id.

[5] Bd of Tr. of the Leland Stanford Junior Univ. v. Roche Molecular Sys. Inc., 487 F. Supp. 2d 1099, 1118 (N.D. Cal. 2007).

[6] Bd of Tr. of the Leland Stanford Junior Univ. v. Roche Molecular Sys. Inc., 583 F. 3d 832, 844-45 (Fed. Cir. 2009).

[7] Id., at 849.

[8] 563 U.S. ____, slip op. at 1.

[9] Justices Sotomayor and Breyer each filed separate opinions, concurring and dissenting, respectively.

[10] 563 U.S. ____, slip op. at 7-8.

[11] *Id.*

[12] *Id.* at 8-9.

[13] *Id.* at 9-13

[14] *Id.* at 13-14.

[15] *Id.* at 15.

[16] *Bd of Tr. of the Leland Stanford Junior Univ. v. Roche Molecular Sys. Inc.*, 563 U.S. ____ (2011) (Breyer, J., dissenting), slip op. at 2.

[17] 563 U.S. ____, slip op. at 5, citing 583 F.3d at 841-42.

[18] *Id.*, at 5 n.2.

[19] 563 U.S. ____ (Breyer, J., dissenting), slip op. at 6-10.

[20] 939 F.2d 1568, 1572 (Fed. Cir. 1991).

[21] 563 U.S. ____ (Breyer, J., dissenting), slip op. at 7.

[22] *Id.* at 10.

[23] *Bd of Tr. of the Leland Stanford Junior Univ. v. Roche Molecular Sys. Inc.*, 563 U.S. ____ (2011) (Sotomayor, J., concurring).