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Who's Billion Dollar Invention Is it Anyway?

A Closer Look at the Supreme Court's Decision Addressing Stanford University's Patent Infringement Case Against Roche Molecular Systems

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June 14, 2011

I. INTRODUCTION

Tracing the arc of 220 years of patent law, the Supreme Court recently placed front and center an individual inventor's ownership interest and held that the Bayh-Dole Act does not automatically vest title to federally funded inventions. *Board of Trustees of Leland Stanford Junior Univ. v. Roche Molecular Systems, Inc.*, 563 U.S. ____, (2011) (slip op.) (Breyer, S., dissenting). The focus of the decision, the Bayh-Dole Act governs the allocation of rights between the Federal government and federal contractors with respect to a federally funded "subject invention." 35 U.S.C. §§201(e), (c), 202(a). A "subject invention" under the Act is "any invention of the contractor conceived or first actually reduced to practice in the performance of work" "funded in whole or in part by the Federal Government." 35 U.S.C. §§201(e), 201(b). The Act provides that contractors may "elect to retain title to any subject invention." 35 U.S.C. §202(a).

As discussed in detail below, in *Stanford University v. Roche Molecular Systems, Inc.*, Stanford University argued that under the Bayh-Dole Act—or the University and Small Business Patent Procedures Act of 1980—it had rights superior to those of the inventor in the invention, which consisted of a highly lucrative test procedure for quantifying levels of the HIV virus in blood samples. Since the patent rights conferred by the Act trumped any other rights in the invention, Stanford maintained, the inventor Dr. Holodniy could not have assigned his rights to Roche, whom Stanford accused of patent infringement.

II. CASE BACKGROUND

A. Scientific Collaboration and Assignment of Rights in Invention

This compelling case involved a Nobel Prize-winning technique of measuring blood-borne levels of HIV. Cetus, a research company later acquired by Roche, developed the technique known as PCR and collaborated with scientists at Stanford to test new AIDS drugs. Dr. Holodniy joined Stanford as a research fellow during that period and in 1988 signed an agreement stating that he "agree[d] to assign" his "right, title and interest in" inventions that resulted from his employment at Stanford. *Stanford v. Roche* (slip op., at 2).

Dr. Holodniy, at the urging of his supervisors at Stanford, later conducted research at Cetus to learn about PCR. Cetus required him to sign a confidentiality agreement stating that he “will assign and doe[es] hereby assign” to Cetus his “right, title and interest in...the ideas, inventions, and improvements” made “as a consequences of [his] access” to Cetus. *Id.* While at Cetus, Dr. Holodniy devised a PCR-based procedure for measuring the levels of HIV in a patient’s blood. At Stanford, he and other Stanford employees tested the procedure. Thereafter, Stanford secured three patents to the measurement process. Roche, having acquired Cetus’s PCR-related assets, commercialized the procedure after conducting clinical trials and today sells its HIV test kits worldwide.

B. Underlying Patent Infringement Dispute: The Road to the Supreme Court

1. District Court Decision

The Board of Trustees of Stanford University filed suit against Roche asserting patent infringement. Roche argued that it had co-ownership of the procedure as a result of Dr. Holodniy’s agreement with Cetus and thus Stanford lacked standing to sue for patent infringement. Stanford countered that since the HIV research was federally funded, the Bayh-Dole Act applied, pursuant to which Stanford had superior rights. As Stanford’s rights trumped, Dr. Holodniy had no right to assign any interest. The District Court agreed with Stanford, but the Court of Appeals for the Federal Circuit reversed.

2. Federal Circuit Decision

Examining the language of the two agreements that Dr. Holodniy executed, the Federal Circuit concluded that under his agreement with Cetus (“I agree to assign and hereby do assign”), Dr. Holodniy had assigned his rights to Cetus and, ultimately, to Roche. In contrast, focusing on the term “agree to assign,” the court concluded that the agreement with Stanford only promised to assign rights to Stanford at a future time. *Id.* at 5. *See also Stanford Junior Univ. v. Roche Molecular Systems, Inc.*, 583 F.3d 832, 841 (2009).

The Federal Circuit also found that the Bayh-Dole Act did not “automatically” void an inventor’s rights in federally funded inventions and thus, Dr. Holodniy was able to assign rights to Roche, as a result of which Stanford lacked standing to sue for patent infringement. *Id.* at 844-45. The Supreme Court agreed with the Federal Circuit’s interpretation of the Bayh-Dole Act, holding that the Act does not automatically vest title to federally funded inventions in federal contractors.

III. STANFORD V. ROCHE AT THE SUPREME COURT

A. The Foundation of Intellectual Property Rights: The Inventor Holds the Rights to his Invention

The Supreme Court’s discussion of the crux of patent law and the “general rule” that rights in an invention belong to the inventor left little room as to how the Court

would interpret the Bayh-Dole Act. The Court succinctly summarized the governing principle as follows: “unless there is an agreement to the contrary, an employer does not have rights in an invention[.]” *Stanford v. Roche*, 563 U.S. ____, No. 09-1159 at 7 (internal citations omitted). As the Supreme Court contemplated it, Stanford and the United States, as *amicus curiae*, urged an interpretation of the Bayh-Dole Act that would “reorder[] the normal priority of rights” in inventions conceived or first reduced to practice with the support of federal funds. *Id.* at 8. Although Congress has enacted statutes that specifically divest inventors of rights in certain inventions—such as those dealing with nuclear material—the Court underscored that such language is “notably absent” in the Bayh-Dole Act. *Id.*

B. Interpretation of the Bayh-Dole Act

To determine the extent of rights conferred to contractors under the Bayh-Dole Act, the Supreme Court parsed the language of the deceptively self-evident provisions. The Court scrutinized the definition of a “subject invention,” which is “any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement.” 35 U.S.C. §201(e) (emphasis added). As noted earlier, contractors may “elect to retain title to any subject invention.” 35 U.S.C. §202(e). Stanford argued that “invention of the contractor” as incorporated in the definition of a “subject invention” includes all inventions of the contractor’s employees created with the aid of federal funding disbursed to the contractor—a broad reading that the Court rejected.

Instead, the Supreme Court construed the phrase “invention of the contractor” to refer to those inventions that are owned by or belonging to the contractor, a category of inventions that does not automatically include inventions made by the contractor’s employees. *Id.* at 9. That the Act allows contractors to “elect to retain title,” reasoned the Court, buttressed Roche’s argument: this language “confirms that the Act does not *vest* title.” *Id.* at 11. Moreover, the Court read the provision to signify that the Act does not confer title to federally funded inventions but rather assures contractors that “they may keep title to whatever it is they already have.” *Id.* at 11. And only when an invention belongs to a contractor does the Act come into play. *Id.* at 12.

The Act’s disposition of rights—like much of the rest of the Bayh-Dole Act—serves to clarify the order of priority of rights between the Federal Government and a federal contractor in a federally funded invention that already belongs to the contractor. Nothing more. *Id.*

Stanford’s reading of the Act, cautioned the Court, would usher a sea change in the landscape of intellectual property rights: under Stanford’s interpretation, an employee’s invention could vest in the University even if the invention were conceived before the inventor was employed with the University, just as long as the invention first reduced to practice was supported by federal funding. The Court continued,

“What is more, Stanford’s reading suggests that the school would obtain title to one of its employee’s

inventions even if only one dollar of federal funding was applied toward the invention's conception or reduction to practice." *Id.* at 14.

In the Court's appraisal, Stanford's construction of the Act rejected the grounding principles of intellectual property law and was thus untenable. *Id.*

C. Renewed Significance of Assignment Agreements

That the Bayh-Dole Act does not automatically vest title to a "subject invention" in the federal contractor is not to say that federal contractors such as Stanford could never possess rights in inventions created by their employees and funded by federal grants. Rather, the Court noted, federal contractors may avail themselves of the "common practice" to obtain assignments from employees. *Id.* at 15. The Court cited guidance documents that the National Institutes of Health, which funded Stanford's HIV research, provides to contractors. These documents state that "an inventor has initial ownership of an invention" by law and thus contractors should "have in place employee agreements requiring an inventor to 'assign' or give ownership of an invention to the organization upon acceptance of Federal funds." *Id.* at 14. The onus, then, falls to federal contractors to execute viable and explicit agreements with employees that require the assignment to the contractor of rights in inventions.¹

With an effective assignment, those inventions—if federally funded—become "subject inventions" under the Act, and the statute as a practical matter works pretty much the way Stanford says it should. *Id.* at 15.

D. Public Policy Considerations Advanced by the United States and Stanford

The Supreme Court, of note, made little reference to the public policy rationales behind the statutory constructions urged by the United States, Stanford and other universities. The Bayh-Dole Act encourages commercialization of inventions, promotes free competition and protects the public through imposition of a set of conditions upon recipients of federal funding. *Id.* (Breyer, S. dissenting at 4); *see also* 35 U.S.C. §200. The dissent by Justice Breyer, joined by Justice Ginsburg, warned that the majority's decision allows individual inventors, for whose invention the public has paid, to avoid the Act's corresponding restrictions and conditions. *Id.* (Breyer, S. dissenting at 4-5). Publicly-funded advances in science can become the purview of private interests who may restrict sales to

¹ Although Stanford had executed an agreement with Dr. Holodniy, the Federal Circuit concluded that the agreement, which used the words "agree to assign," merely granted a promise to assign rights. By contrast, the Cetus agreement stated "I will assign and do hereby assign. . ." The dissent by Justice Breyer referred to the Federal Circuit's interpretation—that the words of the latter agreement operated upon the invention automatically while the former did not—as "mak[ing] too much of too little." *Stanford v. Roche*, (Breyer, S. dissenting at 7).

specific markets and exact unnecessarily high prices, forcing the public to pay twice for the same invention (although there is no guarantee that a university or hospital would not do the same). The *Stanford v. Roche* decision also complicates the marketing and commercialization of inventions, as stressed by the dissent. *Id.* at 5.

E. Practical Implications for Federal Contractors

The Supreme Court's decision resoundingly denies federal contractors, including research universities, hospitals and non-profit research institutions, automatic rights in inventions created by their employees and funded by federal monies disbursed to the respective federal contractor. Had *Stanford* and the United States's construction of the Bayh-Dole act triumphed, contractors would have enjoyed a level of certainty of ownership rights now displaced to murkier territory.

The dissent by Justice Breyer encapsulated the ensuing cause for apprehension. Now, any entity seeking to purchase rights from a contractor would not know for sure whether the contractor itself possesses the patent right or whether an individual employee has—explicitly or inadvertently—assigned the title to a third party. This potential uncertainty raises similar concerns for contractors working with subcontractors on federally funded projects. Contractors must therefore diligently review the language of any agreement that includes provisions addressing assignment of rights to determine if the rights in an invention can be assigned to third parties.

In particular, federal contractors should draft agreements that state that the employee “assigns his rights” rather than “agrees to assign his rights” or “intends to assign his rights.” Additionally, federal contractors should ensure that their subcontracts provide that the subcontractor has obtained assignment of rights from its employees/ inventors. The prime contractor should review the language of the agreements assigning rights from employees to the subcontractor to determine whether the subject agreements preclude or allow for potentially devastating third party assignments.