



FEDERAL CONTRACTS



REPORT

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Intellectual Property

High Noon for Bayh-Dole?



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I. INTRODUCTION.

On February 28, 2011, the U.S. Supreme Court did something it rarely does: hear arguments in a case exploring the intersection of government contracts and intellectual property, specifically *Board of Trustees of Leland Stanford Junior University v. Roche Molecular Systems, Inc.*, Docket No. 09-1159 (hereinafter *Stanford v. Roche*). At issue was whether rights in an invention accorded to federal contractors under the University and Small Business Procedures Act of 1980, 35 U.S.C. §§ 200-12, commonly known as the Bayh-Dole Act, are trumped by an individual inventor's prior assignment of rights. Irrespective of its outcome, the case should raise the antennas of contractors that perform federally funded research and development.

II. THE BAYH-DOLE ACT. The Bayh-Dole Act was conceived out of concern that taxpayers were not obtaining the benefits of their investments in research and development. In this regard, the rules of individual agencies often contemplated that the government would own those inventions that stemmed from taxpayer supported research. The problem with this approach, however, was that the fruits of this federally funded research and development often remained on the government's shelves for far too long, making it to the marketplace after much delay, or not at all. Thus, Congress sought a better way to commercialize its investments.

As expressly stated in Bayh-Dole, Congress sought:

to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the government obtains sufficient rights in federally supported inventions to meet the needs of the government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

35 U.S.C. § 200.

To achieve these objectives, Bayh-Dole established a scheme generally allowing nonprofit and small business government contractors to retain title to federally funded inventions, so long as the Act's procedural requirements are met. In particular, Bayh-Dole states that "[e]ach nonprofit organization or small business firm may . . . elect to retain title to any subject invention" (35 U.S.C. 202(a)), so long as the contractor "disclose[s] each subject invention to the Federal agency within a reasonable time," elects to "retain title to a subject invention," and "file[s] a patent application prior to any statutory bar date . . ." 35 U.S.C. §§ 202(c)(1)-(3). Notwithstanding the contractor's election to retain rights, the U.S. government receives certain minimum rights, including a "paid-up license to practice" the invention (35 U.S.C. § 202(c)(4)), as well as "march-in" rights, permitting it to require the contractor to grant a license in the invention in the event the contractor fails to, among other things, take steps "to achieve practical application" of the invention. 35 U.S.C. § 203. However, if the contractor does not comply with the Act's procedural requirements, the U.S. government "may receive title" to the invention 35 U.S.C. §§ 202(c)(1)-(2). Even if the contractor does not elect to retain title, so long as it complies with the notice requirements, it acquires a irrevocable, royalty-free non-exclusive license, with the right to sublicense. The "Bayh-Dole rights" were extended to large business contractors by Presidential Memorandum on February 18, 1983.

III. STANFORD V. ROCHE. In the case, Stanford sued Roche for infringement of three patents for inventions relating to the detection of the HIV virus. The inventions were purportedly developed by three Stanford employees under funding agreements with the National Institutes of Health ("NIH").

The dispute arose from two agreements signed by one of the inventors, Dr. Holodniy. First, when Dr. Holodniy joined Stanford, he signed its standard Copyright and Patent Agreement ("CPA"), stating in relevant part: "I agree to assign or confirm in writing to Stanford . . . that right, title and interest in . . . inventions . . ." *Stanford v. Roche*, 583 F.3d 832, 841 (Fed. Cir. 2009). Shortly thereafter, in furtherance of his Stanford duties, Dr. Holodniy worked with a company named Cetus to learn polymerase chain reaction ("PCR") technology, the technology underlying the patents at issue. Dr. Holodniy signed a Visitor's Confidentiality Agreement ("VCA") stating he: "will assign and do[es] hereby assign to CETUS, my right, title, and in-

terest in each of the ideas, inventions and improvements . . ." *Id.* at 837.

Dr. Holodniy's research at Cetus produced a test that used PCR to measure the amount of plasma HIV RNA in samples from infected humans. After publishing the findings, Dr. Holodniy returned to Stanford where he and two co-inventors purportedly discovered that the PCR test was an accurate "marker" of the efficacy of anti-HIV drugs. The inventors then filed the parent patent application for the patents at issue. Pursuant to its procedural obligations under Bayh-Dole, Stanford timely notified the government of the inventions and elected to retain title.

Roche, who by then had acquired Cetus' "PCR business," then proceeded to manufacture and sell HIV detection kits using PCR technology. Stanford sued alleging patent infringement. In response to cross motions for summary judgment, the district court rejected Roche's claims of ownership concluding that: (1) they were barred by statute of limitations and laches; and (2) because Stanford complied with the legal requirements of Bayh-Dole, Stanford retained title to the invention and therefore Dr. Holodniy "had no interest to assign." *Stanford v. Roche*, 487 F. Supp. 2d 1099 (N.D. Cal. 2007). Ultimately, however, the district court ruled for Roche, concluding that the asserted patent claims were obvious. *Stanford v. Roche*, 563 F. Supp. 2d 1016 (N.D. Cal. 2008).

On appeal, the Federal Circuit concluded that Roche's claims established an affirmative defense that Stanford lacked standing because it had not joined all co-owners of the invention, specifically Dr. Holodniy. *Stanford v. Roche*, 583 F.3d 832, 848 (Fed. Cir. 2009). Specifically, the court found that Holodniy's CPA with Stanford was an agreement to assign at some undefined future time. By contrast, Holodniy's VCA assignment to Cetus was perfected at signing. Therefore, because Stanford failed to establish that it possessed Holodniy's interests in the patents and because all co-owners must join in an infringement action, Stanford lacked standing to sue. As to the Bayh-Dole Act, the court concluded that Stanford's election of title under Bayh-Dole did not "void[] prior contractual transfers of rights," such as the VCA between Dr. Holodniy and Cetus. *Id.* at 844.

IV. ARGUMENTS.

A. Pro-Stanford. Stanford appealed to the Supreme Court, arguing that Bayh-Dole gave Stanford, as a government contractor, rights in any invention conceived of or first reduced to practice under a federal funding agreement. Stanford argued, among other things, that Bayh-Dole's language created a framework whereby the government contractor (that complies with Bayh-Dole's procedural requirements) would be first in line to get rights in the invention. Brief of Petitioner at 30-38, *Stanford v. Roche*, No. 09-1159 (U.S. argued Feb. 28, 2011).

Bayh-Dole's relevant language states that the "contractor" may elect to "retain title to a subject invention," with the U.S. government "receiv[ing] title to any subject invention in which the contractor does not elect to retain rights." 35 U.S.C. § 202(c)(2). Thus, the small business or nonprofit contractor is first in line to "retain title," followed by the U.S. government.

On other hand, the individual inventor would be last in line. In this regard, the Bayh-Dole Act states, in relevant part:

If a contractor does not elect to retain title to a subject invention in cases subject to this section, the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provisions of this Act and regulations promulgated hereunder.

35 U.S.C. § 202(d). Hence, the argument goes, the individual inventor obtains title where two conditions are met: (1) the contractor does not satisfy the procedural requirement of electing to retain title, and (2) where the individual requests title and the U.S. government chooses to honor that request. *Id.*

The Senate legislative history is consistent with interpreting Bayh-Dole to give the contractor first in line rights:

It has been clearly demonstrated that the universities and nonprofit organizations who are conducting this research effort are much more efficient in delivering these important discoveries to the marketplace than are the agencies. S. 414 will allow such contractors to retain patent rights on these discoveries while allowing the funding agencies to have free access to them.

S. Rep. No. 96-480 at 29 (1979) (emphasis added).

Section 202(a) provides that as a normal rule small business firms and nonprofit organizations are to have the right to elect to retain worldwide ownership of their inventions by making an election within reasonable time after they disclose the invention.

...

Section 202(d) provides agencies with the authority to leave rights with individual inventors in cases when contractors do not elect rights.

Id. at 31, 33 (emphasis added).

The legislative history in the House is also consistent with this view:

Section (a) provides for the acquisition of title to contract inventions by contractors which are either a small business or a nonprofit organization.

...

Section 389 authorizes a contractor's employee-inventor to receive some or all of the contractor's rights to a contract invention if the responsible agency and the contractor approve.

H.R. Rep. No. 96-1307, pt. 2, at 7, 9-10 (1980) (emphasis added). Accordingly, the legislative history, like Bayh-Dole's language, suggests a framework where small business and nonprofit contractors receive title to the invention, and individual inventors only receive title when the contractor chooses not to take it.

B. Pro-Roche. Roche, on the other hand, argues among other things that U.S. patent law rests on the fundamental principle that rights in patents are vested in the inventor, not in the inventor's employer. Brief for Respondents at 19, *Stanford v. Roche*, No. 09-1159 (U.S. argued Feb. 28, 2011). Thus, the language of the Bayh-Dole Act stating that the Act applies to "subject inventions" – 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)) – means that the Act only applies to those rights in inventions that the contractor already owns. Brief for Respondents at 18-20, *Stanford v. Roche*, No. 09-1159 (U.S. argued Feb. 28, 2011). In other words, if the individual inventor did not assign her rights to her employer-contractor, then the contrac-

tor would have no rights in the invention and Bayh-Dole would not apply.

Moreover, Roche argues, Bayh-Dole's language stating that a small business or nonprofit contractor can elect to "retain title" does not mean that the contractor automatically gets title, but rather, it only keeps whatever title it already had. Thus, according to Roche, Bayh-Dole does not contemplate the automatic vesting of title in the contractor.

C. Oral Argument. During oral argument on February 28, two main concerns emerged amongst various justices. First, certain justices appeared concerned about Bayh-Dole's use of the word "retain" and whether it meant "obtain," or "hold onto a title that the organization already has," thereby contemplating that the contractor may not receive full (or any) rights via an assignment from an inventor. In arguing for the former interpretation, Stanford noted that Bayh-Dole's use of the word "retain" was not limited to the contractor's ability to elect to "retain title," but that the statute, section 202(d), also contemplated a contingent "retention of rights by the inventor." Thus, if "retain" only meant that the contractor or inventor gets to keep whatever rights it already has, then Bayh-Dole would make no sense where it contemplates retention of title by the inventor, because to get to that point, the inventor would have no existing ownership right.

Second, some justices seemed concerned about the practical implications of upholding the Federal Circuit's decision. In particular, if title did not pass automatically to the contractor under Bayh-Dole, individual inventors could contract away their rights to federally funded inventions, leaving the U.S. government with nothing. For example, the contractor might agree to allow the inventor to have all rights, but only if the contractor receives royalties stemming from the commercialization of the invention. Under this hypothetical, the contractor would never have rights, and therefore Bayh-Dole would never apply. And as a result, the U.S. government's rights to the invention could potentially be frustrated.

V. IMPACT ON GOVERNMENT CONTRACTORS. Once reached, the court's decision in *Stanford v. Roche* should shake up how the U.S. government, its contractors, and individual third parties that collaborate with those contractors seek to protect their intellectual property interests.

Beginning with the latter, should the court reverse the Federal Circuit's decision, individual third parties that collaborate with nonprofit organizations (including universities) or small businesses will need to pursue a host of protections, including but not limited to seeking assurances from its nonprofit and small business collaborators that they are not performing any part of their work pursuant to a federal funding agreement. If such funding exists, then the third party would probably find itself third in line for the rights to the fruits of such collaboration.

That said, Bayh-Dole's stated objectives may be better served by reversing the Federal Circuit. It is widely accepted that Bayh-Dole has succeeded in ensuring that taxpayer-funded inventions do not sit on the U.S. government's shelves. Indeed, today, there is much more commercialization of taxpayer-funded inventions than there was in 1980. *Innovations Golden Goose*, The Economist, Dec. 14, 2002. The Federal Circuit's deci-

sion raises questions regarding whether such success might continue or whether efforts to encourage federally funded research would be hampered by this change.

For instance, if the Federal Circuit decision is sustained, to preserve their Bayh-Dole rights, nonprofit and small business contractors would need to diligently ensure that employee-inventors do not assign their rights, intentionally or inadvertently, to another entity in a manner that trumps any assignment of such rights to the contractor. Such uncertainty could create a cloud on the contractor's title, potentially reducing the value of the invention itself, or, due to the prospect of limited exclusivity, limiting the contractor's ability to obtain the capital necessary to commercialize the invention. Even if the contractor seeks contractual assurances from its employees that no such assignment exists, the potential that an employee (perhaps unknowingly) signed or signs such an agreement still may create enough uncertainty regarding title to reduce the invention's value.

Moreover, as suggested by Chief Justice Roberts during oral argument, the rule advocated by Roche, where the contractor is only eligible to "retain" whatever interest they already acquired could potentially lead to unwanted results. For example, the inventor and contractor could negotiate a deal: (1) allocating title to the invention to the inventor; and (2) granting the contractor a portion of the royalties. If the inventor possesses

title, then Bayh-Dole arguably would not apply and the U.S. government would not have license rights nor any "march-in" rights to ensure proper commercialization.

In either case, large businesses, which have only been granted Bayh-Dole rights pursuant to a Presidential Memorandum, as opposed to by statute, will now need to take steps to assure that the company enjoys the full scope of the benefits of Bayh-Dole in inventions developed under their federal funding agreements by securing the required assignments for their employees' prospective inventions.

VI. CONCLUSION The Bayh-Dole Act could have done a better job of stating whether title vested in the nonprofit or small business government contractor, on one hand, or the individual inventor, on the other. However, nowhere does the Act state that contractor's rights are contingent upon an effective assignment from the inventor, as the Federal Circuit in *Stanford v. Roche* would suggest. Rather, the Act's language states that individual inventors only obtains title to inventions developed under U.S. funding agreements in instances in which both the contractor and U.S. government elect not to take title. Moreover, adopting Stanford's interpretation of Bayh-Dole does the most for achieving the Act's stated objectives of encouraging commercialization of taxpayer-funded research.