***STANFORD V. ROCHE*:**

**IMPLICATIONS FOR THE FUTURE**

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**INTRODUCTION**

In its decision in *Stanford v. Roche*, 131 S. Ct. 2188 (2011), the Supreme Court held that the Bayh-Dole Act does not automatically invest title to a federally funded invention to a University or non-profit entity without a pre-existing assignment from the inventor to the entity. In light of this holding, several questions arise for entities that perform research with the aid of federal funding. This article briefly examines the Court’s decision and its implications for the future.

# The crux of the dispute in *stanford v. roche*

The *Stanford v. Roche* case focused on the proper interpretation of certain key provisions of the Bayh-Dole Act. The case arose in the following context:

Dr. Holodniy was a Stanford research fellow operating under several federal grants for HIV research. When he joined Stanford’s Department of Infectious Disease in July of 1988, he signed Stanford’s standard Copyright and Patent Agreement. He specifically “agree[d] to assign … to Stanford” his intellectual property rights “as required by Contracts or Grants.” Pet. App. 119a. The Agreement prohibited Dr. Holodniy from “enter[ing] into any agreement creating copyright or patent obligations in conflict with this agreement.” For approximately nine months in 1989, Dr. Holodniy spent one or more afternoons a week at a research facility owned by a private company called Cetus, which has subsequently been acquired by Roche. Dr. Holodniy consulted with several Cetus scientists about ways to use a technique that Cetus had developed, Polymerase Chain Reaction or (“PCR”) to assist with HIV diagnosis or treatment. When Dr. Holodniy began his work at Cetus, he signed something called a “Visitor’s Confidentiality Agreement,” which provided that he could not disclose any confidential Cetus information. But it also contained a provision stating that Dr. Holodniy “hereby assign[ed] to Cetus my right” to any inventions conceived or reduced to practice “as a consequence of my access to Cetus’s facilities or information.” After he had completed his work at Cetus, Dr. Holodniy and colleagues from Cetus and Stanford published an article describing their work and suggesting that further research was necessary to be able to apply the PCR assay that they had worked on to meaningful HIV diagnosis or treatment. When he returned to Stanford full-time, Dr. Holodniy and his Stanford colleagues performed extensive studies and clinical experiments and ultimately developed a technique and protocol for using PCR to measure the effectiveness of HIV treatment in patients. Stanford filed a patent application for this technique and protocol in May 1992.

Because the work done by the Stanford researchers was funded by the NIH, the resulting discovery was a “subject invention” governed by the Bayh-Dole Act. 35 U.S.C. § 201(e). Pursuant to the Act’s provisions, Stanford timely submitted an invention disclosure form to the NIH in 1992 and confirmed the grant of a nonexclusive, nontransferable, irrevocable, paid-up license in the patent application to the Government as required. In 1995, Stanford timely perfected its rights to the patent under the Bayh-Dole Act by formally notifying the Government that it elected to retain title. *See* 35 U.S.C. § 202(c)(2). It was undisputed that Stanford had satisfied all requirements of the Bayh-Dole Act to perfect its title to the subject inventions.

Cetus was eventually acquired by Roche, which developed a commercially successful HIV monitoring product that used the technique and protocol patented by Stanford. In 2000, Stanford offered Roche an exclusive license to the Stanford’s patented technique and protocol, and the parties negotiated for several years. During those negotiations, Roche never suggested that it had an ownership interest in Stanford’s patents. After the parties’ negotiations failed, Stanford sued Roche in 2005 for patent infringement. Roche responded and argued that it possessed an ownership interest in the patents because of Dr. Holodniy’s assignment of rights in the Visitor Confidentiality Agreement that he had signed at Cetus. The district court rejected Roche’s ownership claim, holding both that California’s four-year statute of limitations and the doctrine of laches barred Roche from asserting an ownership claim more than four years after it learned of Stanford’s patents and that the Bayh-Dole Act vested title in the invention to Stanford, rather than Dr. Holodniy, so that Dr. Holodniy had no interest to assign to Cetus. However, the district court ruled that Stanford’s patents were invalid as obvious in light of the article that Dr. Holodniy and his colleagues had published about their work at Cetus.

Stanford appealed to the Federal Circuit, which did not address the obviousness issue, but instead held that Stanford lacked standing to assert patent infringement because Roche had an ownership interest in the Stanford patents as a result of the Visitor’s Confidentiality Agreement that Dr. Holodniy had signed at Cetus. The Federal Circuit thus held that the Bayh-Dole Act did not vest Stanford with title to the invention, but rather that Dr. Holodniy retained title as the inventor and could assign that title to Cetus. In doing so, the Federal Circuit held that the “agree to assign” language in Dr. Holodniy’s original assignment to Stanford was trumped by the “hereby assign” language in Cetus’s Visitor’s Confidentiality Agreement.

In the Supreme Court, Stanford argued that the provision of the Bayh-Dole Act permitting a university or non-profit entity to “retain title” to an invention that was conceived or reduced to practice using federal funds, 35 U.S.C. § 202(a), as well as the definition of a “subject invention” as an invention “of the contractor,” particularly when read in conjunction with the other provisions of the statute, automatically vested title in such invention to a university or non-profit entity that complied with the various requirements set forth in Section 202(c). Historically, the Bayh-Dole Act was enacted in the aftermath of two conflicting regimes for determining ownership in federally funded inventions. Several federal agencies had been subject to “vesting statutes” that expressly provided the title to federally funded inventions to the government. The other regime used by several federal agencies involved a licensing approach in which the federal government would merely receive a license to practice inventions made through the use of federal funds. “ The mere complexity of these policies constitute[d] a very real hurdle to universities, nonprofit organizations, and small businesses who do not have large legal staffs to negotiate through this policy maze.” S. Rep. No. 96-480, at 2-3 (1979). Under Stanford’s view of the case, the Bayh-Dole Act was meant to formalize the vesting statute approach across all federal agencies. A principal purpose of the statute was to get government-funded patents off of government shelves and those inventions produced and made available to the public. Stanford therefore argued that the point of the Bayh-Dole Act is to vest title in a federal contractor that complies with the requirements of the statute, but leave the Government with residual rights, including those set forth in the statute to “march in” and require title if an invention were not being pursued commercially. *See* 35 U.S.C. § 203.

Thus, Stanford interpreted Section 202(c) of the statute to list the steps a university or non-profit entity must take to be provided with title to a covered invention. Thus, the language permitting the entity to “retain title” to the invention would apply either to those entities that had obtained title under the vesting statute or obtained title by following the steps prescribed in the statute. Stanford also argued, in the alternative, that the word “retain” in common usage can refer either to keeping something already acquired, or actually acquiring something in the first place. Stanford further argued that the definition of a “subject invention” as an “invention of the contractor” connoted an invention developed by a contractor and its employees, rather than acquired by an assignment; one generally does not refer to something like the writings of Emerson or the decision of the court as something acquired rather than authored by the object of the phrase. Thus, Stanford urged that the only reasonable way to read the language of the statute was to provide title to the covered entity without requiring a separate assignment of title from the inventor to the covered entity. Under Stanford’s reading, inventors only have tertiary rights to title in covered inventions, that they could exercise only when both the federal contractor and the Government have been unable or have declined to retain title. *See id.* § 202(d).

Roche argued that, as the Federal Circuit had held, the Bayh-Dole Act does not automatically vest title of a covered invention in a university of non-profit entity that complies with the requirements of Section 202(c) of the statute, but rather that title vests in the inventor, absent an assignment to a university or other entity or to the government. Roche urged that the typical rule in patent law is that ownership vests in the inventor and that there is no clear language in any single provision of the statute that vests title in a university or other entity. Roche and its amici also argued that there could be several practical problems if title were to vest in a university or other entity, particularly involving collaborations between academia or government scientists and private industry.

The Supreme Court ultimately held that the Bayh-Dole Act does not automatically vest title of covered inventions in universities and non-profit entities, but rather that title is vested in the inventor, absent an assignment. The Court’s opinion begins:

Since 1790, the patent law has operated on the premise that rights in an invention belong to the inventor. The question here is whether the University and Small Business Patent Procedures Act of 1980 – commonly referred to as the Bayh-Dole Act displaces that norm an automatically vests title to federally funded inventions in federal contractors. We hold that it does not.

131 S. Ct. at 2192. The Court acknowledged that the prior vesting statutes had provided title to federally funded inventions to government agencies, but emphasized that clear vesting language “is notably absent from the Bayh-Dole Act. Nowhere in the Act is title expressly vested in contractors or anyone else.” *Id.* at 2196. The Court disagreed that the statutory language permitting a contractor to elect “to retain title” or the language stating that the Act covered inventions “of the contractor” is vesting language: “We are confident that if Congress had intended such a sea change in intellectual property rights it would have said so clearly – not obliquely through an ambiguous definition of ‘subject invention’ and an idiosyncratic use of the work ‘retain.’” *Id.* at 2196-97.

Justices Breyer and Ginsburg dissented. They would have returned the case to the Federal Circuit to address whether the “agree to assign” language in Dr. Holodniy’s original assignment to Stanford should take precedence over the “hereby assign” language in Cetus’s Visitor’s Confidentiality Agreement. *Id.* at 2202-03. Justice Sotomayor concurred in the opinion of the Court, but noted that she shared Justice Breyer’s concerns on this point. *See id.* at 2199. For its part, the majority noted that “[b]ecause the Federal Circuit’s interpretation of the relevant assignment agreement is not an issue on which we granted certiorari, we have no occasion to pass on the validity of the lower court’s construction of those agreements. *Id.* at 2194 n.2.

# implications of the decision for the future

There are several implications of the *Stanford v. Roche* decision, both practical and doctrinal:

## The Impact on Government, University and Non-Profit Assignments

Perhaps the most obvious affect of the Court’s decision will be with respect to government, university and non-profit assignments. The decision has clarified that title does not automatically vest in a federal contractor or the government under the Bayh-Dole Act. Accordingly, government agencies, universities and non-profit entities will need to ensure that they obtain assignments from their employees to perfect their title to inventions that they produce in the scope of their employment.

There are also significant implications for the language used in assignments. There are a plethora of government, university and non-profit assignments that use the “agree to assign” language that the Federal Circuit held was trumped by a later assignment using “hereby assign” language. Thus, such entities will likely try to rewrite those assignments, and will very likely use different language for future assignments. However, there is the prospect of significant litigation for those entities over ownership disputes centering on the use of the “agree to assign” language. It may not be possible to avoid such litigation simply by rewriting those assignments now, given that the litigation will likely involve past-assignments that parties claim trump preexisting assignments with the “agree to assign” language.

Moreover, such entities will likely try to be extremely vigilant regarding any documents that their employees sign in the future. Stanford had no knowledge of the Visitor’s Confidentiality Agreement signed by Dr. Holodniy until litigation had commenced (and for his part, Dr. Holodniy did not remember ever signing that document and was not provided a copy of it). Thus it would behoove government, universities and non-profit entities to ensure that their employees do not sign any documents that contain assignments of rights unless those entities know about and approve such assignments. But this is easier said than done. Government agencies, universities and non-profits typically do not have extensive resources or personnel to ensure that employees do not sign any problematic assignments. Accordingly, one possible consequence of the Court’s ruling would be to motivate such entities to increase the resources they devote to protecting intellectual property and to ensuring that their employees do not sign any unapproved assignments.

## The Impact on the Federal Circuit’s Assignment Doctrine

Another implication of the *Stanford v. Roche* decision is that it will likely lead to one or more challenges to the Federal Circuit’s precedent holding that “agree to assign” language is trumped by more definitive language such as “hereby assign.” The Federal Circuit’s doctrine on this point stems from its decisions in *FilmTec Corp. v. Allied-Signal, Inc.*, 939 F.2d 1568 (Fed. Cir. 1991) and *Arachnid, Inc. v. Merit Industries, Inc.*, 939 F.2d 1574 (Fed. Cir. 1991). In *FilmTec*, the Court held that “hereby assign” constitutes a present-tense assignment of a further invention, while in *Arachnid*, the Court held that “will be assigned” language does not vest title to future inventions. Thus, the Federal Circuit in *Stanford v. Roche* held that the “agree to assign” language in Dr. Holodniy’s original assignment to Stanford did not actually vest Stanford with title to future inventions. Justice Breyer noted that this present/future tense distinction is not persuasive. “Given what seems only a slight linguistic difference in the contractual language, this reasoning seems to make too much of too little.” 131 S. Ct. at 2202-03 (Breyer, J., dissenting). And of course, Justice Ginsburg, who joined Justice Breyer’s dissent, and Justice Sotomayor agree with this concern. Moreover, the majority did not express any view to the contrary.

Particularly given the general principle cited by Justice Breyer that any assignment to rights in a future assignment provides only equitable, rather than legal title, to such an invention, *see, e.g.,* G. Curtis, A Treatise on the Law of Patents for Useful Inventions § 170, p. 155 (3d ed. 1867), it appears that the Federal Circuit’s doctrine on this point is susceptible to challenge. It is reasonable to expect that such challenges will occur in the near future and that the Supreme Court may be inclined to resolve this issue, now that it has arisen in the *Stanford v. Roche* case.

## The Impact on the Patent Reform Act

Another possible effect that the decision may have is on certain of the innovations in the recently enacted Patent Reform Act. Several provisions of that Act are designed to streamline inventorship disputes and have effectively adopted a strong presumption of inventorship in an applicant who is the “first to file” a patent application. However, the *Stanford* opinion suggests that the old “first to invent” regime may be constitutionally mandated. *See* 131 S. Ct. at 2188 (citing U.S. Const. Art. 1 § 8, cl. 8). While it is not clear that there is a direct conflict between the decision and the Patent Reform Act, it is certainly possible that the Act will be subject to exacting scrutiny by the courts, and ultimately the Supreme Court, and it is not a foregone conclusion that all of its provisions will withstand that scrutiny.

## Effects on Future Legislation

Finally, the Court’s decision strongly suggests that when Congress intends to change the normal rules of patent law in a particular context it must do so in clear, unmistakable language. Whether the decision has implications beyond patent law remains to be seen, but it is apparent that the argument made by Roche and its amici that any change in ordinary patent-law rules could have significant unintended consequences resonated with the Court.