

## Client Alert.

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June 6, 2011

# Supreme Court Holds Bayh-Dole Act Does Not Grant Contractors Patent Ownership Rights to Federally Funded Inventions

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The Supreme Court today, for the first time, interpreted the Bayh-Dole Act, a federal statute regulating ownership of patents arising from federally funded research, and gave it a narrower scope than many had traditionally understood it to have.

The Supreme Court's decision in *Board of Trustees of Leland Stanford Junior University v. Roche Molecular Systems, Inc.* No. 09-1159, rejected the arguments of Stanford University and the United States that the Bayh-Dole Act vested title to federally funded inventions with the eligible federal contractor (e.g., universities, non-profit organizations, or small businesses). The Supreme Court instead held that the Bayh-Dole Act permits contractors only to retain title to patents that they already possessed through other means, such as assignment provisions in employment contracts with the inventors.

Although the Court concluded that any threat that its decision posed to the effectiveness of the Bayh-Dole Act could be avoided by contractual arrangements between the federal contractors and their employee-inventors, the Court's decision could raise significant questions about the ownership rights for innumerable inventions made prior to the Court's decision. The Court's decision also will affect the possibilities of commercializing federally funded inventions, requiring those who seek to purchase rights from contractors to evaluate the rights held by the contractor *vis-a-vis* the inventor and any third parties with whom the inventor has contracted.

### 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.<sup>1</sup> 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.<sup>2</sup>

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

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<sup>1</sup> 35 U.S.C. § 202(a).

<sup>2</sup> *Stanford*, slip op. dissent at 3-4.

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named assignee of the patent-in-suit, as a result of written assignments from the inventors after the invention was made. 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.<sup>3</sup>

In 2005, Stanford sued Roche Molecular Systems, Inc. (“Roche”) for patent infringement in the Northern District of California, claiming that Roche’s HIV test kits infringed Stanford’s patents. Roche, which had acquired Cetus, alleged ownership of the asserted patents as both a counterclaim and an affirmative defense.

The Federal Circuit ruled in favor of Roche. It held that, unless the federal government exercises its rights under the Bayh-Dole Act, titles to inventions made under federal contracts remain with the named inventors or their assignees, and the Bayh-Dole Act does not “void[] prior contractual transfer of rights.”<sup>4</sup> 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.<sup>5</sup> On the facts before it, and as discussed below, the Federal Circuit concluded that one of the named inventors, Mark Holodniy, had assigned his invention to Cetus, not Stanford, and thus Roche was not liable for infringement.<sup>6</sup>

## THE SUPREME COURT DECISION

In a 7-2 opinion authored by Chief Justice Roberts, the Supreme Court affirmed the Federal Circuit’s judgment. The Court started from “the general rule that rights in an invention belong to the inventor” and that “an inventor must expressly grant his rights in an invention to his employer if the employer is to obtain those rights.”<sup>7</sup> It then concluded as a matter of statutory interpretation that the Bayh-Dole Act did not alter this normal priority of rights for federally funded inventions.

The Court relied on the Bayh-Dole Act’s definition of “subject invention” as “any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement.” It concluded that the phrase “of the contractor” referred to inventions “owned by or belonging to the contractor,” not merely inventions made with the aid of federal funding. The Court noted that Congress had in the past used unambiguous language to deem inventions created pursuant to specific federal contracts the property of the United States, not the inventor, and the absence of such language in the Bayh-Dole Act also suggested that Congress did not intend a similar result under that Act.<sup>8</sup>

The Court looked to other provisions of the Bayh-Dole Act to support its conclusion. It explained that the “Bayh-Dole Act’s provision stating that contractors may ‘elect to *retain* title’ confirms that the Act does not *vest* title.”<sup>9</sup> Similarly, the Court found that the Act’s provision allowing the government to “grant requests for retention of rights by the inventor” “assumes that the inventor had rights in the subject invention at some point, undermining the notion that the Act automatically vests

<sup>3</sup> *Stanford*, slip op. at 1-2, 4.

<sup>4</sup> *Bd. of Trs. of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 583 F.3d 832, 844 (Fed. Cir. 2009).

<sup>5</sup> *Id.*

<sup>6</sup> *Id.* at 841-42.

<sup>7</sup> *Stanford*, slip op. at 7-8.

<sup>8</sup> *Id.* at 9 (quoting 35 U.S.C. § 201(e)).

<sup>9</sup> *Id.* at 11 (quoting 35 U.S.C. § 202(a)).

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title to federally funded inventions in federal contractors.”<sup>10</sup> Finally, the Court found that the Bayh-Dole Act’s lack of procedures to protect the rights of inventors and third parties confirmed that it is limited to regulating the rights between the contractor and the government when the contractor has already acquired title to an inventor’s interest.

Ultimately, the Supreme Court concluded that Congress would not have intended to depart from “one of the fundamental precepts of patent law and deprive inventors of rights in their own inventions” without doing so far more clearly and with greater protections for the rights of the inventor.<sup>11</sup> The Court justified its conclusion as a matter of policy by noting that universities typically eliminate any potential problems from inventors holding title in federally funded inventions by entering into assignment agreements with their employees that convey title in inventions to the universities.

Justice Breyer, joined by Justice Ginsburg, dissented, arguing that the Bayh-Dole Act was enacted against a background norm that often denied inventors patent rights in inventions arising from federally funded research. The dissent further argued that the statute sought to distribute rights in federally funded inventions in ways that further the public interest in commercialization and marketing of inventions paid for by the public. In this context, the dissent rejected the majority’s conclusion that an inventor could remove an invention from the scope of the Bayh-Dole Act simply by assigning an invention made with public funds to a third party. The dissent would have vacated the Federal Circuit’s judgment and remanded for further briefing on whether, among other things, for purposes of ownership of inventions, employees of federally funded employers should be treated more like federal employees (who do not have rights in their inventions) than private employees.

## THE IMPACT OF THE STANFORD DECISION

Although it will take some time to determine the true impact of the Supreme Court’s decision in *Stanford*, there is no doubt that it will have a major effect on the scores of inventions made with the assistance of federal funding.

Because federal contractors can no longer rely on the Bayh-Dole Act to provide title to inventions, they will need to ensure that their agreements with their employees are sufficient to automatically convey title in inventions to the contractor. In addition, contractors will need to determine whether their employees have entered into any pre-existing agreements with third parties that would trump its own assignment rights and what, if anything, can be done about that.

*Stanford* also creates significant uncertainty regarding already existing, commercially viable inventions that were created with federal funds. Those seeking to acquire rights to such inventions from contractors will need to review the language used in any potentially relevant agreements involving the inventor and determine the respective rights of the inventor, the contractor, any commercial partners of the inventor or contractor, and other third parties. And those against whom patents on these inventions are enforced undoubtedly will seek discovery regarding any prior relationships or agreements by the inventor that could undermine the patentee’s standing to bring suit.

Much of the practical future import of the decision could relate to an issue that the Court declined to address, *i.e.*, the meaning attributed to the two assignments at issue. Prior to undertaking the research that led to the patents-in-suit, Holodniy signed a Copyright and Patent Agreement with Stanford in which he “agree[d] to assign” his “right, title, and interest in” inventions resulting from his employment at the University. But Holodniy subsequently conducted research at

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<sup>10</sup> *Id.* at 12 (quoting 35 U.S.C. § 202(d)).

<sup>11</sup> *Id.* at 14.

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Cetus's facilities and signed a Visitor's Confidentiality Agreement 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.

The Federal Circuit had held that the language "agree to assign" in the earlier document "reflects a mere promise to assign rights in the future, not an immediate transfer of expectant interests." By contrast, the Federal Circuit held that the "do hereby assign" language in the later "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. 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."<sup>12</sup>

Both the dissent and Justice Sotomayor's concurrence questioned the logic of the Federal Circuit's distinction between the language of present assignment (e.g., "do hereby assign") that automatically conveys legal title in an invention and the language of future assignment (e.g., "agree to assign") that does not. Although the majority had "no occasion to pass on the validity of the lower court's construction" of the agreements because it was not an issue on which certiorari was granted,<sup>13</sup> the doubts expressed by at least three justices are sure to generate further litigation and consideration of this issue in the future.

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<sup>12</sup> 583 F.3d at 841-42.

<sup>13</sup> *Id.* at 5 n.2.