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Patents

High Court's *Stanford* Ruling Puts Special Demands on Life Sciences, Attorneys Say

■ **Case Summary:** *The Supreme Court holds that the Bayh-Dole Act does not bar inventors from assigning their individual rights in patents resulting from federally funded research.*

■ **Key Takeaway:** *Attorneys say that those involved in life sciences-related research in particular must take care to perform due diligence in assessing the research institution's title to the inventions.*

Attorneys and life sciences companies expressed concern that, as a result of the Supreme Court's June 6 ruling that the Bayh-Dole Act does not bar inventors from assigning their individual rights in patents resulting from federally funded research, a research organization's efforts to properly secure rights to that invention will become more complicated and more demands will be placed on life sciences research than on other areas (*Bd. of Trustees of Leland Stanford Junior University v. Roche Molecular Systems Inc.*, U.S., No. 09-1159, 6/06/11).

In a dispute over patents on HIV technology, the court, in a 7-2 vote, rejected Stanford University's argument that the act automatically vests patent title to universities and other contractors for inventions resulting from research financed at least in part by federal funds.

Carl Gulbrandsen, of the Wisconsin Alumni Research Foundation, in Madison, Wis., was disappointed with the decision. "It's going to force all the universities to be much more careful in looking at the agreements their faculty are entering," he said. He noted that the assignment in the instant case came in a confidentiality agreement, and WARF does not require faculty to disclose such agreements.

Matthew B. McFarlane of Robins, Kaplan, Miller & Ciresi LLP, New York, told BNA that the "decision clarifies that universities and other research institutions cannot rely solely on the provisions of the Bayh-Dole Act as a universal sword to rescue and secure rights to inventions that may have been supported by funding from the federal government. Like all other employers, these entities need to obtain specific assignment agreements or obligations to assign from their employees and students whose work may result in a future invention."

The ruling underscores the importance of obtaining effective assignments of inventions made using government funding and also presents practical challenges, Judith Hasko of Latham & Watkins, Menlo Park, Calif., told BNA.

"Research institutions will need to assess whether the assignment clauses in their agreements with researchers will be effective in light of this decision, and if these clauses are not, such institutions will need to alter the language in those agreements to be effective. However, research institutions finding deficiencies in their invention assignment clauses face some practical challenges in changing agreements that they have used for years, and which have been approved by many institutional stakeholders," Hasko said.

District Court Sides with Roche, Federal Circuit Reverses. Bayh-Dole—formally the University and Small Business Patent Procedures Act of 1980, 35 U.S.C. §§ 200-212—has a comprehensive set of rules for allocating patent interests among the government, the "contractor"—generally a university or small business—that the government funded, and the individual inventors listed on the patents.

Just as with any private company, a contractor conducting research funded by the government can eliminate any question of individual researchers' rights to patents arising from the research through appropriate assignment contracts. The instant case arose because Stanford University's employment agreement required researchers to "agree to assign" patent rights to the university.

A Stanford employee, Mark Holodniy, on loan to a private research lab that now is part of Roche Molecular Systems, signed a confidentiality agreement that immediately assigned to Roche patent rights in future inventions: "I will assign and *do hereby assign*" intellectual property rights.

The patents at issue (5,968,730, 6,503,705, and 7,129,041) involve correlating measurements of HIV nucleic acids to determine whether a particular therapy is effective. Holodniy conceived the procedure while at Roche, then returned to Stanford to conduct clinical studies. Stanford subsequently filed for and was issued the patents. After licensing negotiations with Roche failed, Stanford filed a lawsuit alleging that Roche's HIV detection kits infringed the patents.

The U.S. District Court for the Northern District of California granted Stanford's motion for summary judgment as to whether Roche was an owner of the dis-

puted patents or had a license, thus rejecting Roche's claim that Stanford lacked standing without Holodniy's assignment.

On appeal, the Federal Circuit reversed. The court held that Roche was co-owner of the patents—along with Stanford—because Holodniy had assigned his rights to Roche prior to conception of the invention, 583 F.3d 832 (3 LSLR 985, 10/9/09).

The Supreme Court granted certiorari Nov. 1 (4 LSLR 1017, 11/5/10) on the question: "Whether a federal contractor university's statutory right under the Bayh-Dole Act, 35 U.S.C. §§ 200-212, in inventions arising from federally funded research can be terminated unilaterally by an individual inventor through a separate agreement purporting to assign the inventor's rights to a third party."

Oral arguments were held Feb. 28, with the U.S. solicitor general participating as *amicus curiae* in support of Stanford's position (5 LSLR 217, 3/11/11).

Bayh-Dole Text Dooms Stanford's Arguments. "Although much in intellectual property law has changed in the 220 years since the first Patent Act, the basic idea that inventors have the right to patent their inventions has not," said Chief Justice John G. Roberts Jr., writing for the majority. "Only when an invention belongs to the contractor does the Bayh-Dole Act come into play."

The majority rejected Stanford's argument that this result would fundamentally undermine Bayh-Dole, asserting that current university practice resolves the problem.

Roberts first identified the court's precedents going back to 1851 that "confirm the general rule that rights in an invention belong to the inventor."

"It is equally well established that an inventor can assign his rights in an invention to a third party," Roberts said, citing *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 188 (U.S. 1933). Also, he asserted, the *Dubilier* court held "that unless there is an agreement to the contrary, an employer does not have rights in an invention 'which is the original conception of the employee alone.'"

Rejecting the view of Stanford and the U.S. government that Bayh-Dole trumps those rules, the court distinguished other legislation that specifically vested intellectual property rights in the United States—certain inventions on nuclear materials and atomic energy, in 42 U.S.C. § 2182; pursuant to NASA contracts, in 51 U.S.C. § 20135(b)(1); or funded by the Department of Energy, in 42 U.S.C. § 5908.

"Such language is notably absent from the Bayh-Dole Act," the court explained. "Nowhere in the Act is title expressly vested in contractors or anyone else; nowhere in the Act are inventors expressly deprived of their interest in federally funded inventions."

The parties contested whether the phrase "any invention of the contractor" in the definition of "subject inventions" in Section 201(e) of the act, 35 U.S.C. § 201(e), was meant to cover any invention made by the contractor's employees or any invention owned by or belonging to the contractor. The high court agreed with the latter rendering.

You Cannot 'Retain' Unless You Already Have. Another part of the Bayh-Dole text working against Stanford is a provision, Section 202(a), that allows contractors to "elect to retain title" to a Bayh-Dole subject invention. "You cannot retain something unless you already have

it," the court said. "The Bayh-Dole Act does not confer title to federally funded inventions on contractors or authorize contractors to unilaterally take title to those inventions; it simply assures contractors that they may keep title to whatever it is they already have."

Section 210(a) begins, "This chapter shall take precedence over any other Act which would require a disposition of rights in subject inventions," but the court rejected the solicitor general's argument that the phrase overturns the individual inventor's rights. The court noted again that the act applies only to "subject inventions," as it had previously construed that term.

"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," Roberts said. "Nothing more."

Current Practice Confirms Interpretation. The court then looked at current practice in university employment agreements and found further support.

For example, the court referred to guidance by the National Institutes of Health to contractors, that "[b]y law, an inventor has initial ownership of an invention" and that contractors should therefore "have in place employee agreements requiring an inventor to 'assign' or give ownership of an invention to the organization upon acceptance of Federal funds."

Thus rejecting Stanford's contention that the court's decision threatens the continued success of Bayh-Dole, the court said, "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. The only significant difference is that it does so without violence to the basic principle of patent law that inventors own their inventions."

The court thus affirmed the Federal Circuit's decision.

Justices Antonin Scalia, Anthony M. Kennedy, Clarence Thomas, Samuel A. Alito, Sonia Sotomayor, and Elena Kagan joined the opinion.

Dissent Contests Majority's Interpretation of Text. Justice Stephen G. Breyer dissented. He argued that the Federal Circuit's focus on the assignment language in the employment and confidentiality agreements at issue "seems to make too much of too little." He would instead treat both agreements as merely creating equitable rights, and then address the Bayh-Dole questions—not adequately briefed in the case below and so necessitating remand—within that context.

First, Breyer argued that the ability of an individual inventor to assign to a third party inventions resulting from public funding is "inconsistent with the [Bayh-Dole] Act's basic purposes. It allows individual inventors, for whose invention the public has paid, to avoid the Act's corresponding restrictions and conditions. And it makes the commercialization and marketing of such an invention more difficult."

Breyer next contended that the text of the Bayh-Dole Act was not so clear cut to support the majority's view. He concluded that the phrase "invention of the contractor" must refer to its employees' inventions, since a contractor does not conceive of ideas or reduce them to practice "other than through its employees." He left as an open question, though, whether "the term 'subject

invention' also include[s] inventions that the employee fails to assign properly."

Rejecting the majority's reliance on "background norms of patent law," Breyer posited that Bayh-Dole created "competing norms governing rights in inventions for which the public has already paid, [which] along with the Bayh-Dole Act's objectives, suggest a different result."

Dissent Contests Federal Circuit's Contracts Rule. Finally, Breyer faulted the Federal Circuit for its rule on assignment language in contracts.

The majority said, in a footnote, "Because the Federal Circuit's interpretation of the relevant assignment agreements 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."

However, Breyer addressed squarely the appeals court's analysis that favored the Roche contract. "Given what seem only slight linguistic differences in the contractual language, this reasoning seems to make too much of too little." Citing older treatises on patent law, he contended that "a present assignment of future inventions (as in both contracts here) conveyed equitable, but not legal title."

With both Stanford and Roche thus having only equitable interests in Holodny's invention, he said, Stanford's prior agreement meant that it should have prevailed.

Breyer thus criticized the Federal Circuit for making "a significant change in the law" in *FilmTec Corp. v. Allied-Signal Inc.*, 939 F. 2d 1568 (1991). "While the cognoscenti may be able to meet the *FilmTec* rule in future contracts simply by copying the precise words blessed by the Federal Circuit, the rule nonetheless remains a technical drafting trap for the unwary."

He interpreted the majority's footnote as not foreclosing a future challenge to the Federal Circuit's rule, and because it is "relevant to our efforts to answer the question presented here," said that he would vacate the appeals court's judgment and remand the case for more adequate briefing on the issue.

Justice Ruth Bader Ginsburg joined Breyer in dissent. In a one-paragraph concurrence, Justice Sonia Sotomayor also criticized the Federal Circuit's *FilmTec* reasoning, but agreed with the majority because Stanford failed to challenge the decision on those grounds.

Donald B. Ayer, of Jones Day, Washington, represented Stanford. Mark C. Fleming, of WilmerHale, Boston, represented Roche. Deputy Solicitor General Malcolm L. Stewart represented the government.

Stanford Disagrees, Others See Pluses, Minuses. Stanford University issued a statement respectfully disagreeing with the decision, citing Justice Breyer's statement in his dissent that the majority's ruling would allow an individual inventor at a university, nonprofit, or small business to "assign an invention (produced by public funds) to a third party, thereby taking that invention out from under the Bayh-Dole Act's restrictions, conditions and allocation rules," and that is "inconsistent with the Act's basic purpose."

Stanford wrote that it, the federal government, and Sen. Evan Bayh in his amicus brief had argued that this result was not the intent of Bayh-Dole and has many potential negative consequences for the federal government, which retains certain rights to inventions created with federal funding, for universities and others who

create inventions with that funding, and for companies that license the inventions.

"For example, the federal government could lose its many rights in the inventions, could lose the assurance that the royalties that would have gone to the university are used to further scientific research and education, and could lose the requirement that exclusive licensees will manufacture any products substantially in the United States," Stanford wrote.

The statement said that, while the university was disappointed with the ruling, it will move forward to protect the interests of all parties in inventions created with federal funding, including the interests of the federal government and companies that license technology from Stanford.

"I think the court reached the decision that will cause the least panic," Steve S. Chang, of Banner & Witcoff, Washington, told BNA. "By saying that Bayh-Dole does not automatically transfer ownership, ownership of inventions will be decided under the same terms they have been for many, many years—starting with the inventor, and looking for a chain of assignment agreements. Had the decision gone the other way, it could have raised questions in any assignment that was made by an inventor to someone other than the inventor's employer, something that often happens as companies partner with universities."

However, William D. Coston, of the Venable law firm, Washington, who wrote a brief on behalf of one of the bill's authors, Bayh, expressed concern. "The decision could add expense to what is already very expensive patent litigation by having discovery focused on whether all the paperwork is consistent with an inventor's assignment of his or her interest to the university," he said.

He faulted the court for "its explicit focus on the text of the statute" and for not paying enough attention to the legislative intent of the Bayh-Dole Act. On the other hand, Coston said, "Going forward, the fundamental purpose of the act remains intact, and it is simply incumbent on universities to make sure their paperwork is in order."

"From Sen. Bayh's perspective," he said, "while that's an important issue, it's ancillary to the principal beauty of the act, getting inventions in the hands of the universities."

More Demanding for Life Sciences. The Biotechnology Industry Organization (BIO) issued a joint statement with the Association of American Universities, the American Council on Education, the Association of Public and Land-grant Universities, the Association of University Technology Managers, and the Council on Governmental Relations, noting that the biotechnology industry and the university community rely on effective collaborations to make the products of their research and development available to the public. "Although BIO and the undersigned higher education associations held different views on the *Stanford v. Roche* case, the organizations are united in the desire to ensure that the U.S. technology transfer system continues to generate these public benefits through the robust provisions of the Bayh-Dole statute. We are committed to working together in light of the Supreme Court's decision to ensure the continued vibrancy of public-private partnerships and success of our shared objectives."

McFarlane assessed the effect of the ruling on life sciences research. "In some ways, the task of identifying and securing rights to an invention may be more demanding in life sciences versus other research areas, in part because of the scale of NIH's funding (relative to agencies that fund other disciplines) directed to relatively basic research programs," he said. "At early stages of research and development, an invention may not be clearly identifiable or even capable of sufficient description given the Federal Circuit's en banc restatement of the written description requirement of 35 U.S.C. s. 112, first paragraph in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*"

To the extent that progress in the life sciences increasingly depends on the contribution of different individuals and areas of expertise, "federal funding to any of the research programs contributing to a downstream invention might complicate the analysis of how a research organization should proceed in properly securing rights to that invention," McFarlane said.

Hasko stressed the need for those involved in life sciences-related research to take care to perform due diligence in assessing the research institution's title to the inventions.

"For example, they should review the assignment agreements the inventors executed with the research

institution, where possible (such agreements may not easily be traced, and may not be made available to the proposed licensee)," Hasko said. "Licensees should be aware that even if an invention-specific assignment agreement has been executed by the inventors in a patent filing, if the general assignment clause in the inventor's agreement with the research institution was ineffective, and if the inventor executed an effective assignment clause in an agreement assigning title to the invention to an entity other than the research institution prior to executing the invention-specific assignment to the research institution, it is possible that the invention may not be owned by the research institution."

Hasko noted that research institutions often provide minimal assurances in license agreements either supporting their title to the funded inventions, or confirming that third parties do not have an ownership interest in such inventions. "This makes it even more important to perform due diligence inquiries on assignment and title prior to licensing government-funded inventions," she said.

BY TONY DUTRA AND JOHN T. AQUINO

The court's opinion is available at <http://pub.bna.com/ptcj/091159Jun6.pdf>.