

A Client Update From GCA's Litigation Group

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THIS ISSUE

This IP Update highlights a case now pending before the United States Supreme Court concerning patent ownership rights as between inventors, private industry and the government in inventions developed using governmental grants. The outcome of the Court's ruling in this case may dramatically impact how companies handle, and contractually address, such development in the future.

Stanford University v. Roche: Supreme Court Holds Oral Arguments Concerning Patent Ownership Rights for Inventions Developed in Government Funded Research

On February 28, 2011, the United States Supreme Court heard oral argument in *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, et al.*, No. 09-1159, to consider whether carefully contractual assignment agreements trump the Bayh-Dole Act in determining ownership rights in inventions developed with federal funding.

THE BAYH-DOLE ACT

Also known as the University and Small Business Patent Procedures Act, the Bayh-Dole Act is codified in 35 U.S.C. § 200-212, and implemented by 37 C.F.R. 401. Adopted in 1980, among other things, the Act gave U.S. universities, small businesses and non-profits the ability to control rights over inventions and other intellectual property that resulted from governmental funding by essentially shifting the presumption of ownership to the university or non-profit in priority

to the government, while preserving certain "march-in rights" that enables the government to license inventions.

BACKGROUND OF THE DISPUTE

In the mid-1980's, Cetus Corporation (Cetus) developed a scientific technique called polymerase chain reaction (PCR). In 1989, Dr. Mark Holodniy, a researcher from Leland Stanford Junior University (Stanford), briefly worked as a visitor at Cetus's facilities, where he first conceived of a commercial application of PCR for the detection and quantification HIV levels in patients' blood. Dr. Holodniy then returned to Stanford and participated in federally funded clinical trials of the PCR application, which eventually resulted in Stanford being granted three related patents, each of which name Dr. Holodniy as the inventor.

When Dr. Holodniy joined Stanford, he signed a "copyright and patent agreement" pursuant to which he agreed "to assign" inventions to Stanford. Additionally, Dr. Holodniy signed a "visitor's confidentiality agreement" with Cetus, in which he assigned rights to any inventions devised as a "consequence" of his work at Cetus's facilities. Hoffman-Roche, Inc. ("Roche"), the Swiss Company that acquired Cetus, later commercialized the PCR application without either entering into a license with or paying royalties to Stanford. Starting in

1996, Roche sold kits to quantify HIV levels in blood to hospitals and clinics worldwide. Roche refused Stanford's demands to enter into a license and pay royalties, and Stanford sued Roche for patent infringement in 2005.

Roche claims ownership of Dr. Holodniy's PCR application based upon the 1989 contract Dr. Holodniy signed while working at Cetus, which contained a provision granting Dr. Holodniy's inventor ownership rights to Cetus for inventions Dr. Holodniy conceived of while working as a visitor at Cetus's facilities. The District Court held that the Bayh-Dole Act barred Roche's ownership claims and that Stanford, therefore, owned the patents.

On appeal, the Federal Circuit U.S. Court of Appeals reversed in part. The Federal Circuit explained that Dr. Holodniy's contract with Stanford did not compromise Cetus's rights under the 1989 contract because Dr. Holodniy had only agreed to assign Stanford his inventor ownership rights to Stanford in the future. In contrast, under the 1989 contract, Dr. Holodniy agreed to assign Cetus both his present and future rights. The Federal Circuit said that the Cetus agreement, in which included the phrase "do hereby assign," took effect immediately, trumping the "I agree to assign" language of the Stanford agreement, which the Federal Circuit characterized as a promise of future action. In addition to addressing these contract issues, the Federal Circuit held that the Bayh-Dole Act did not negatively impact Roche's rights obtained acquisition of Cetus, finding that the "statutory scheme did not automatically void the patent rights that Cetus received from Holodniy." The Federal Circuit held, therefore, that Roche had co-ownership of the patents by virtue of the Cetus confidentiality agreement signed by Holodniy. Because standing principles preclude a patent suit by one co-owner without all other co-owners' agreement and participation, the Federal Circuit concluded that Stanford lacked standing, and reversed the District Court's ownership decision.

The Supreme Court granted Stanford's petition for certiorari in November, and set the matter for oral argument on February 28, 2011.

In its Petition to the Supreme Court, Stanford argued its ownership rights to Dr. Holodniy's PCR application were not contingent upon it receiving an effective assignment from Dr. Holodniy because, under the Bayh-Dole Act, inventor rights are subordinate to those of Stanford and the government. Stanford argued that the Federal Circuit's decision conflicts with the clear hierarchy of rights provided in the Bayh-Dole Act.

SUPREME COURT HEARING

At oral argument, Donald B. Ayer of Jones Day argued on behalf of petitioner Stanford that the Bayh-Dole Act "specifically defines the rights of inventors" as standing "in the third position, behind the contractor . . . and behind the government." Mr. Ayers further argued that an inventor receives rights in the invention only ". . . when the contractor has declined to take title or defaulted in some respect, and the government has likewise declined to take title."

Roche's attorney, Attorney Mark C. Fleming of Wilmer Cutler Pickering Hale & Dorr urged the Court to give Bayh-Dole its "straightforward meaning." Fleming argued the statute's "laudable" objective of "taking government inventions off the shelves and putting them into the market" should not replace the high court's "longstanding" rule that title to an invention rests with its inventor.

Arguing for the government, Deputy Solicitor General Malcolm Stewart warned that, if upheld, the Federal Circuit's ruling could have wide-ranging repercussions.

CONCLUSION

As evidenced by the tremendous attention this case has received in the industry, the Court's ruling may have a dramatic impact on the rights of private industry, universities and the government. More than 25 amici curiae, or legal opinions, to the Court in this case. In one, jointly filed by the Intel Corporation, Eli Lilly and Company, and Johnson and Johnson, and others, the companies argued that granting Stanford patent rights could reduce opportunities for the public to benefit from the invention and be a disincentive toward future development. The Obama administration and

others argue that federally funded research projects are meant "to advance the public interest," as opposed to corporate profit, and that the government should be permitted to protect the taxpayer's investments in such research and development.

The *Stanford* case underscores the importance under current law of careful drafting in assignment documentation, particularly where federal funding is involved. Until such time as the Supreme Court

renders a ruling, and if the Court upholds the Federal Circuit ruling with little comment or revision, companies will be well advised to give greater attention to the scope and terms of their assignment agreements.

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