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The Supreme Court Did Not Alter Who Owns Federally Funded Inventions in *Stanford v. Roche*

BY JOSEPH P. ALLEN AND HOWARD W. BREMER

In an article titled ''Who Owns Federally Funded Research? The Supreme Court and the Bayh-Dole Act,'' which appeared in the *New England Journal of Medicine*, Dr. Aaron Kesselheim and Dr. Rahul Rajkumar argue that the Supreme Court ruling in *Stanford v. Roche* requires an amendment to the Bayh-Dole Act to restore university ownership of inventions made with federal funding.[1]

Such a conclusion fundamentally misunderstands the ruling. The law continues to work precisely as it did before the Supreme Court decision.

They also demonstrate a flawed understanding of how the Bayh-Dole Act (Pub. L. No. 96-517) functions. Despite the criticisms embedded in Kesselheim-Rajkumar's writing, the Bayh-Dole Act has been a tremendous boon to public health worldwide—and the growth of the U.S. economy.

Before Bayh-Dole, the government policy was to acquire title to federally funded inventions, thereby taking them away from their creators and negating the incentives of the patent system. Subsequently, few government-owned inventions were turned into products benefiting the taxpayer. For example, Congress found that not one drug had been developed and marketed from National Institutes of Health research under these policies.[2]

The Bayh-Dole Act was passed in 1980 to correct that failing by providing universities and small companies conducting federally funded R&D with an incentive to own and commercialize resulting inventions. The resulting impact is underscored by an article in *NEJM*, which found 153 new drugs, vaccines, or new uses for existing drugs were commercialized because of Bayh-Dole.[3]

The claims of the authors Drs. Kesselheim and Rajkumar that ''important new drugs and medical technologies are developed in university or nonprofit settings supported by federal funding and later commercialized with little return to these development sources'' reflects a misunderstanding of how this process works.[4]

Academic inventions tend to be embryonic in nature, not useful products. Moreover, universities do not, and should not, develop their inventions to market-ready condition. When licensing inventions to an industry partner for commercial development, any monetary return to a university depends upon commercial success. However, the basic premise of Bayh-Dole is to transfer the inventive technology for the public benefit—not to generate university income.

Joseph P. Allen is president of Joseph Allen and Associates, Bethesda, Ohio. Allen was a professional staff member for Sen. Birch Bayh on the Senate Judiciary Committee and helped move the Bayh-Dole Act through Congress. He later oversaw implementation of the law at the U.S. Department of Commerce.

Howard W. Bremer is patent counsel emeritus at the Wisconsin Alumni Research Foundation, Madison, Wis. Bremer co-authored and negotiated the Institutional Patent Agreements codified by the Bayh-Dole Act with both the National Institutes of Health and the National Science Foundation. He was a central figure in creating support for Bayh-Dole in Congress.

[1] Aaron S. Kesselheim and Rahul Rajkumar, ''Who Owns Federally Funded Research? The Supreme Court and the Bayh-Dole Act,'' *NEJM*, Vol. 365, No. 13, p. 1168.

[2] University and Small Business Patent Procedures Act, Report of the Committee on the Judiciary, U.S. Senate, on S. 414, Dec. 12, 1979, Rept. No. 96-480, p. 21.

[3] Ashley J. Stevens, Jonathan J. Jensen, Katrine Wyller, Patrick C. Kilgore, Sabarni Chatterjee, and Mark L. Rohrbaugh, ''The Role of Public-Sector Research in the Discovery of Drugs and Vaccines,'' *NEJM*, Feb. 10, 2011, p. 535.

[4] See *supra*, note 1.

Developing a new drug can easily cost more than $1 billion, requiring over a decade of work. Even then there is no guarantee of market success. This expense—and risk—is borne by the private sector. The dearth of new drug development worldwide is a growing concern. This is no venture for the faint of heart.

Drs. Kesselheim and Rajkumar also misunderstand the Supreme Court's ruling in *Stanford v Roche,* claiming that it denies universities ''the first rights to the fruits of publicly funded research. This outcome now requires a legislative amendment to Bayh-Dole.''[5]

This simply is not the case.

The facts behind *Stanford v. Roche* are complex. Briefly, Dr. Mark Holodniy joined Stanford University to work on AIDS research. He signed Stanford's standard agreement that any invention arising from his employment would be assigned to the university after it was made.

Dr. Holodniy's supervisor had an ongoing relationship with Cetus, which had won a Nobel Prize for an AIDS detection technique. The supervisor wanted Holodniy to work at Cetus as a visiting scientist, making the necessary arrangements. Upon his arrival at Cetus, Dr. Holodniy signed the required visiting scientist agreement stipulating that he assign to the company any inventions made as a consequence of his access to their research.

Here's how the Supreme Court describes what happened next:

> Working with Cetus employees, Holodniy devised a PCR [polymerase chain reaction]-based procedure for measuring the amount of HIV in a patient's blood. Upon returning to Stanford, he and other Stanford employees tested the procedure. Stanford secured three patents to the measurement process.[6]

Cetus was acquired by Roche, which began selling HIV test kits worldwide. Stanford approached Roche asking it to take a license to their patents on which Dr. Holodniy was a named inventor, claiming that the Roche kits infringed Stanford's patents. Roche declined, saying that the Stanford patents were based on research Dr. Holodniy had performed at Cetus, and the company, therefore, co-owned the patents.

Unable to agree, the dispute headed to court.

At trial, Stanford argued that Roche was trying to use Dr. Holodniy's visiting scientist agreement to acquire rights to patents made solely from federally funded research that the university owned under the Bayh-Dole Act. Roche countered that Stanford was attempting to ignore the contribution that their privately funded research made to the inventions as a result of Dr. Holodniy's visit.

Thus far it was a fairly typical patent ownership dispute. However, as the case was appealed through the court system, a new argument arose questioning a fundamental premise of the patent law. In arguing that the Supreme Court should review the lower court rulings, the U.S. solicitor general held that Bayh-Dole automatically ''vested'' invention rights in universities without the need to obtain written consent from their researchers.

U.S. patent law requires that inventors, not organizations, must file for patents. It is well established that employed inventors can be required to assign rights to inventions made at work to their employers. By arguing that such written consent was not even needed under Bayh-Dole, the focus of the dispute changed completely.

Recognizing a question involving fundamental principles of law, the Supreme Court agreed to hear *Stanford v. Roche*.

We were involved in the development and passage of Bayh-Dole, and warned that the ''vesting'' argument was a misrepresentation of how the law worked. There is no basis for it in the law, the legislative history, or the implementing regulations. We pointed out that in the 30 years that Bayh-Dole had been in place, universities always had their researchers sign agreements giving the school rights to federally supported patents.

Nevertheless, Stanford made the ''vesting'' theory a centerpiece of its subsequent argument before the Supreme Court. That turned out to be a fatal miscalculation.

In its ruling, the Court ignored the disputed facts of who funded the inventions in question, focusing squarely on the vesting theory. The Court soundly rejected vesting, as it contradicted the thrust of the U.S. patent law since its enactment in 1790. The Court said that universities must have the written consent of their employed inventors in order to own inventions under Bayh-Dole. Thus, despite the claims of Drs. Kesselheim and Rajkumar, the ruling leaves Bayh-Dole working as it did before the case arose.

There are, however, some important lessons from *Stanford v. Roche*:

- Any organization placing researchers in another facility must understand the consequences of intellectual property ownership agreements their scientists usually will be required to sign.
- University invention assignment agreements should immediately convey patent ownership, not do so in the future.
- Faculty needs to understand the implications of signing consulting agreements promising rights to intellectual property to outside entities. Their university employers need to know when these exist.
- If inventions are made with contributions by the private sector, rights accruing to those contributions must be acknowledged even if there is federal funding involved that is covered by Bayh-Dole.

Finally, Bayh-Dole continues to work as intended—and we are all better off for it.

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[5] Ibid.

[6] *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems Inc.*, U.S., No. 09-1159, on writ of certiorari to the U.S. Court of Appeals for the Federal Circuit, June 6, 2011, p. 2.

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