

# The Supreme Court Decision in Stanford v. Roche (2011) : Implications for the University

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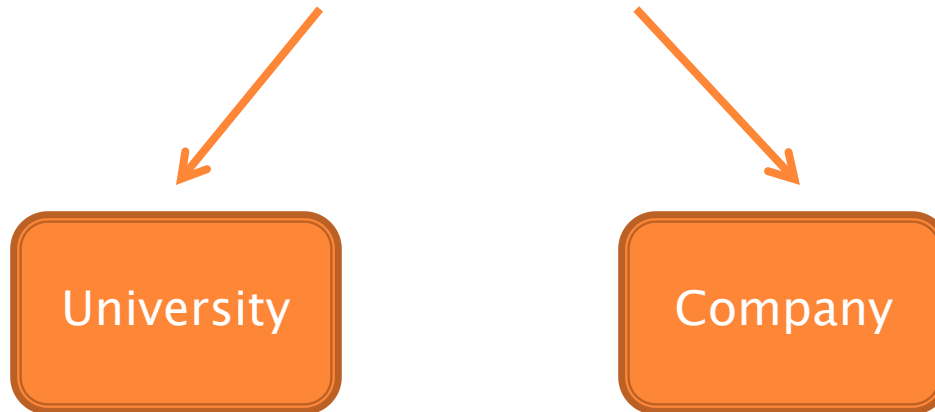
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# Stanford v. Roche

## ISSUE

What happens when a University researcher assigns his/her rights in a federally funded invention to a company?

Who owns the invention?



# Bayh–Dole Act (35 USC §§200–212)

- ▶ Enacted on December 12, 1980
- ▶ Controls ownership of federally funded inventions with regard to small businesses and non–profits.
- ▶ Allocates rights as between federal contractors and Government
- ▶ Allows federally funded entities to “elect to retain title to any subject invention\*” ....

\*any invention of the contractor conceived or first reduced to practice.....under a funding agreement

# Bayh–Dole

## Basic Purpose

- ▶ Promote the utilization and commercialization of inventions arising from federally supported research for public benefit
  - Promote academic–industry collaborations

# Bayh–Dole

## Before

- ▶ US owned 28,000 patents
- ▶ Less than 5% of patents were licensed
- ▶ Only granted non-exclusive licenses
- ▶ Never assigned ownership
- ▶ Technology not being developed

## After

- ▶ More than 5,000 new university based startups since 1980
- ▶ Patents issued to universities increased from 495 in 1980 to 3,278 in 2005
- ▶ Private research support to academia grew 76% from 1980–2006
- ▶ Paved way for development of federally funded technology

# Stanford v. Roche

## Facts

- ▶ Stanford had federally funded research (HIV detection method), subjecting it to Bayh–Dole. Stanford followed Bayh–Dole requirements.
- ▶ In 1988, Inventor(Dr. Holodniy) joined lab at Stanford as post–doc.
- ▶ Inventor’s project was to develop improved method for quantifying HIV levels in blood using PCR.
- ▶ In 1980’s, Cetus (small California biotech) perfected and improved the PCR method. First PCR patent in 1985.
- ▶ In 1989, Inventor went to Cetus as visiting scientist to learn more about PCR.

# Stanford v. Roche

## Assignments



- ▶ **Inventor signed a Copyright and Patent Agreement with Stanford (1988)**
  - He “agree[d] to assign” to Stanford his “right, title and interest in” inventions resulting from his employment at Stanford
- ▶ **To gain access to Cetus, he signed a Visitor’s Confidentiality Agreement(VCA)(1989)**
  - Stated that the inventor “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.

# Stanford v. Roche

- ▶ Inventor and Cetus employees developed a PCR based procedure for quantifying the amount of HIV in blood.
- ▶ Upon return to Stanford, he and other Stanford employees tested the measurement process.



# Stanford v. Roche

## The Lawsuit Begins

- ▶ In 1991, Cetus acquired by Roche.
- ▶ Stanford eventually secured 3 patents.
  - Filed application in 1992
  - Executed another assignment 1995
  - Retained title 1995
  - Issue dates 1999, 2003, 2006
  - Cetus(Roche) never applied for a patent on that procedure.
- ▶ 1995, Roche began selling PCR-based HIV test kits.
- ▶ Stanford alleged infringement by Roche and asked Roche to take a license. (2000–2004)
- ▶ Roche refused. Stanford sued for infringement in 2005.

# Stanford v. Roche

## Roche's Argument

- ▶ VCA made Roche joint owner of the patents, and free to practice the inventions.
- ▶ No license necessary.
- ▶ Stanford has no standing to sue.
- ▶ Patents invalid.

## Stanford's Argument

- ▶ 1. The inventions were made under federally sponsored research that Holodniy had assigned to Stanford. Owned by Stanford under Bayh-Dole.
- ▶ 2. Holodniy had no rights to assign to Roche because Stanford's HIV research was federally funded. Bayh-Dole gave them superior rights in the invention.

# Stanford v. Roche

## Stanford's Argument

- ▶ 3. “Elect to retain title” language means that title automatically vests in contractor.
- ▶ 4. “Invention of the contractor” means inventions made by the contractor’s employees with federal funding.
- ▶ 5. Construing Bayh–Dole as not vesting title to federally funded inventions in federal contractors fundamentally undermines the Act’s framework and threatens its continued successful application.

# Stanford v. Roche

## Questions Addressed by Court

- ▶ Does the Act operate to automatically vest title in the federal contractor?
- ▶ How does the contractor receive title?
- ▶ Can an individual inventor, through a separate agreement, assign his rights in the federally funded invention to a 3<sup>rd</sup> party?

# Stanford v. Roche

## Trial History

- ▶ **District court (2007)**
  - VCA effectively assigned rights to Cetus(Roche), but because of Bayh–Dole, Holodniy had no rights to assign.
  - Individual inventor may obtain title only after government and contractor have declined to do so.
  - Dismissed Roche’s claim of ownership.
  - Ruled patents invalid.

# Stanford v. Roche

## Federal Circuit(2009)

- ▶ Holodniy effectively assigned rights to Cetus(Roche)
- ▶ Affirmed Dist. Ct. dismissal of Roche ownership counterclaim(based on S/L) but ruled in favor of Roche ownership as affirmative defense.
  - “Roche possessed an ownership interest in the patents” that was not extinguished by Bayh–Dole
- ▶ Remanded to Dist. Ct. to dismissal Stanford claim of infringement

# Stanford v. Roche

## Supreme Court addresses Stanford's arguments(2011)

Argument 1. The inventions were made under federally sponsored research that Holodniy had assigned to Stanford. Owned by Stanford under Bayh-Dole.

- ▶ Court said its precedents confirm the general rule:
  - Ownership lies with inventor who can assign his rights in an invention to a third party.

# Stanford v. Roche

Argument 2. Holodniy had no rights to assign to Roche because Stanford's HIV research was federally funded. Bayh-Dole gave them superior rights in the invention.

- ▶ Court said Stanford wrong in thinking Bayh-Dole gives universities priority over inventors.
  - Act does not reorder the priority.
  - In Stanfords view the "Act moves inventors from the front of the line to the back."



# Stanford v. Roche

Argument 3. “Elect to retain title” language means that title automatically vests in contractor.

- ▶ Court said:
  - Use of that language confirms that the Act does not automatically vest title.
  - You cannot retain title unless you already have it.
  - Act does not confer title to contractors; it assures they can keep title to what they already have.
  - For university to gain ownership, inventor has to assign.
  - Upon assignment, contractor gains title and can then elect to retain title.

# Bayh-Dole

## Requirements to elect to retain title

- ▶ Disclose each subject invention to Federal agency within reasonable time
- ▶ Make a written election within 2 years after disclosure
- ▶ File a patent application prior to any statutory bar date
- ▶ Government obtains
  - Nonexclusive, paid-up license
  - March in rights
- ▶ If no election by federal contractor, Government may consider and grant requests for retention of title by inventor

# Stanford v. Roche

Argument 4. “Invention of the contractor” means inventions made by the contractor’s employees with federal funding.

▶ Court said:

- Mere employment is not sufficient to vest title to an employee’s invention in the employer; thus a contractor’s invention does not automatically include employee’s inventions.
- Obtain assignment



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# Stanford v. Roche

Argument 5. Bayh–Dole not vesting title federal contractors fundamentally undermines the Act’s framework and threatens its continued successful application.

- ▶ Court said with an effective assignment, those inventions become subject inventions under the Act.

# Stanford v. Roche

## Supreme Court's Decision(7-2)

- ▶ Stanford lost.
- ▶ Court affirms Federal Circuit.
  - Dismissed Stanford's infringement claim(no standing)
  - Holodniy effectively assigned to Cetus
  - Ownership by Roche
    - No ownership by inventor or Stanford
    - No royalties to inventor or Stanford
    - Roche still selling kits

# Stanford v. Roche

## Questions Answered

- ▶ Does the Act operate to automatically vest title in the federal contractor? No
- ▶ How does the contractor receive title? Through effective assignments from employees
- ▶ Did the inventor, through the VCA assign his rights in the federally funded invention to Cetus? Yes(even though there were multiple inventors)

# Stanford v. Roche

## Why did Stanford lose?

- ▶ I agree to assign.....
  - Ineffective
  - Agreement to make an assignment in the future.
  - Requires later assignment.

## Contrast with the Cetus assignment.

- ▶ I will assign and hereby assign.....
  - Present assignment to the future inventions.
  - Effective immediately and as soon as invention made.

# Stanford v. Roche

## Bayh–Dole after Stanford

### ▶ Unchanged

- Does not automatically vest title in contractor
- Bayh–Dole is junior to patent law.
  - Rights initially vest with the inventor
- Comes into play only when invention belongs to contractor.
  - Clarifies rights as between government and contractor.



# Stanford v. Roche

## What the Decision Means To You

- Any agreement that you or a co-inventor sign with an external party could significantly affect your ownership rights in your inventions.
- Bayh-Dole is not a safe harbor.
- You need to protect your rights!

# Stanford v. Roche

## How Can We Protect Ourselves

- ▶ Have assignments with effective language.
  - “...strong unambiguous assignment language”. John P. Moran– Partner, Holland and Knight
- ▶ Monitor relationships with industry
  - Don’t sign agreements without consulting UTRF or attorney
- ▶ Educate peers, postdocs, students on implications of signing industry agreements

# Stanford v. Roche

## Is UT Protected?

### ▶ **UT IP policy**

- “Domestic and foreign rights to certain inventions and creations developed by University personnel in performing the duties of their employment by the University or through their substantial use of facilities or funds provided by the University shall be assigned to the University.....”
- “....shall be part of the conditions of employment.....”
- Available through UTRF’s website ([utr.f.tennessee.edu](http://utr.f.tennessee.edu))

### ▶ **No employment agreement assigning rights to inventions to UT**

- Faculty appointment letter agreeing to be bound by university bylaws and policies
- UTRF and UT General Counsel currently drafting appropriate assignments for presentation to campus administration and faculty senates

### ▶ **UTRF obtains assignment upon disclosure(doesn’t prevent Stanford situation)**

- “The University hereby assigns and agrees to assign to UTRF its entire right, title, and interest throughout the world in and to the Subject Technology.”
- “Each of the Originator(s) hereby assigns and agrees to assign to UTRF.....”

# Contact Us

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