28th Annual Ounce of Prevention Seminar

Welcome

Predicting the Future:
Federal Contracting in an Election Year

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STANFORD v. ROCHE AND WHAT IT MEANS FOR THE BAYH-DOLE ACT AND CONTRACTORS

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Bayh-Dole Act – The Basics

- University and Small Business Patent Procedures Act of 1980, 35 U.S.C. §§ 200-212 (aka "the Bayh-Dole Act")
- Served as uniform replacement for numerous patent policies then existing in federal agencies
- Generally permits non-profits & small business government contractors that satisfy certain procedural requirements to retain rights in inventions conceived or first reduced to practice in performance of work under a government contract, grant, or cooperative agreement between the Government and the government contractor
- USG retains paid-up license to practice or have practiced on its behalf as well as other unique rights, *i.e.*, march-in rights
- Extended to large businesses by Executive Order

“Subject Invention”

- Bayh-Dole applies to “subject inventions”
  - “Subject invention” = “any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement”
  - “Funding agreement” = “any contract, grant, or cooperative agreement entered into between any Federal agency, other than the Tennessee Valley Authority, and any contractor for the performance of experimental, developmental, or research work funded in whole or in party by the Federal Government”

  35 U.S.C. § 201 (emphasis added)

Disposition of Rights

- Right to Retain Title
  - Nonprofits or small business firms may “elect to retain title to any subject invention”
  - USG has paid-up, worldwide license to practice or have practiced for or on behalf of USG
  - USG “may receive title” where contractor does not elect to retain rights
  - USG may “grant requests for retention of rights by the inventor” if contractor does not elect to retain title

35 U.S.C. § 202 (emphasis added)

Stanford University v. Roche Molecular

- Stanford's Patents – related to methods for detecting and quantifying the amount of HIV in blood samples using polymerase chain reaction (PCR)
- 3 Inventors
- Dispute arose from two agreements signed by one inventor, Dr. Holodniy

Assignments

- Stanford hired Holodniy in 1988 as Research Fellow
  - Signed Copyright & Patent Agreement (CPA) with Stanford
  - "I *agree to assign*…right, title and interest in…such inventions"
- Stanford sent him to Cetus to learn polymerase chain reaction (PCR) technology
  - Holodniy signed Visitor's Confidentiality Agreement (VCA) with Cetus
  - "I…do hereby assign to CETUS, my right, title, and interest in each of the ideas, inventions and improvements" devised "as a consequence" of work at Cetus

The Patents

- At Cetus, Dr. Holodniy produced test using PCR technology that test the efficacy of anti-HIV drugs
  - Invention conceived at CETUS
- Returned to Stanford and further refined and tested the invention under US Government funding agreement
- Stanford disclosed inventions as “subject inventions” to USG and notified USG of election to retain title
- Stanford obtained a further assignment agreement from Holodniy
- Three patent applications filed
- Patents issued in 1999, 2003, and 2006

The Dispute

- Roche acquired all of Cetus' PCR-related assets in 1991
  - Began producing and selling HIV detection kits using the patented PCR technology worldwide
- Stanford approached Roche about Roche taking a license to their patents – Roche refused
- Stanford sued for patent infringement
- District Court
  - Stanford satisfied Bayh-Dole procedural requirements so retained title to inventions
  - Because of Bayh-Dole, Dr. Holodniy had no interest to assign to Cetus
- Federal Circuit
  - When Stanford elected to retain title under Bayh-Dole, Dr. Holodniy had already assigned the patent rights to Cetus
  - Essentially added to Bayh-Dole a prerequisite that the contractor employee assign patent rights to the government contractor employer

U.S. Supreme Court

- Federal Circuit decision upheld
- Rationale:
  - Inventor is first to own is longstanding rule of law
    - Employment alone does not vest ownership in employer
    - No unambiguous language divesting employee-inventors of title
  - Bayh-Dole did not expressly change this longstanding rule
    - "Subject invention" / "Invention *of the contractor*"
      - Refers to inventions already owned by the contractor
      - "of the contractor" would be unnecessary if title automatically vested with the contractor under Bayh-Dole

U.S. Supreme Court

- Rationale (continued):
  - "Elect to *retain* title"
    - "Confirms that Act does not vest title"
    - "'Retain' means 'to hold or continue to hold in possession or use"
    - But see Sec. 202(d):

      If a contractor does not elect to retain title to a subject invention in cases subject to this section, the Federal agency may consider and after consultation with the contractor grant requests for *retention of rights* by the inventor

      - Court distinguishes – Inventor could have an assignment agreement, with subsidiary rights to the inventor

Potential Problems with Court's Holding

- Focused narrowly on a few, arguably ambiguous terms:
  - "The term 'subject invention' means any invention *of the contractor"*
  - "Each nonprofit organization or small business firm may . . . *elect to retain title* to any subject invention"
- Efficacy of Bayh-Dole now contingent on language of inventor assignment agreement
- *Stanford v. Roche* creates ownership uncertainty
  - Nonprofits/small business will never know for sure whether inventors have signed away their rights
- Revising Bayh-Dole to automatic vest title with the contractor as opposed to the inventor reduces dependency on assignments, which can be confusing and subject to different interpretations

Potential Problems with Court's Holding

- Impact of *Stanford* on Bayh-Dole's objectives
  - Uncertainty of clear title = less incentive to collaborate
    - Bayh-Dole seeks to "promote collaboration between commercial concerns and nonprofit organizations" (35 U.S.C. § 200)
  - Uncertainty of clear title = less incentive to innovate & commercialize
    - Uncertainty of ability to recoup through future sales or licenses
    - Potential reduction in invention's value
    - Increased due diligence costs to try to prove a negative (*i.e.*, there is no other assignment)
      - Undermines Bayh-Dole's express objective: "to minimize the cost of administering policies in this area" (35 U.S.C. § 200)

What Stanford Means for Contractors

- Don’t depend on Bayh-Dole for automatic title
- Assignments…assignments...assignments
  - Take care with the language
- Know what your employees are doing with collaborators
- Seek assurances from employees that there are no conflicting assignments
- Subcontractors & collaborators
  - Follow the money
  - Whose IP will be used?
  - Assignments…assignments…assignments