

# **Prop. 71 and the “Bayh-Dole model”**

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# Overview

- The Bayh-Dole Act of 1980: Content
- “Effects” of Bayh-Dole
- A “Bayh-Dole model” and Prop. 71.

# **The Bayh-Dole Act of 1980: Content**

- Rationalized and simplified federal policy toward assignment of patent rights, licensing.
  - Political statement as important as statutory provisions.
- BD Act delegated management to research performers and reduced agency oversight of licensing of federally funded research results.
  - Under BD, federal agencies have the following authority:
    - Royalty-free, nonexclusive license to the patent
    - “March in” rights to mandate licensing of a patented invention (never invoked thus far)
    - Power to deny patent rights to a contractor/inventor “in exceptional circumstances” (invoked once).

# **The Bayh-Dole Act of 1980: Content**

- Many US universities (MIT, Stanford, UC) were active patenters before BD Act's passage.
  - Patenting & licensing were allowed under agency-specific “Institutional Patent Agreements” (IPAs) negotiated by each university.
  - HEW efforts in 1970s to limit exclusive licensing by U.S. universities of NIH-funded inventions strengthened universities' support for passage of BD.
  - Act is an effect, as well as a cause, of increased US university patenting.

# The Bayh-Dole Act of 1980: Effects

- University patenting increased, buuuut.....
  - Other factors are as important as Bayh-Dole.
    - *Chakrabarty* & *Diehr* decisions, USPTO policy evolution; NIH funding of biomedical research; universities' search for revenues after DoD research support declines in early 1970s.
  - Many of the inventions patented in the immediate aftermath of BD appear to be less important than pre-BD patents, at some “experienced,” many novice institutional patenters.
- How large is the pot of licensing gold?
  - UC systemwide gross revenues averaged \$77M/year for FY 2001 – 2004; net licensing contributions to UC systemwide & campus operating budgets averaged \$16M/year, less than 1% of annual UC research budget.
    - Industry sponsored \$235M of research at UC in FY 2003.
  - Gross licensing revenues at UC, Stanford, Columbia, elsewhere are dominated by small # of patents, majority of which cover biomedical inventions.

# The Bayh-Dole Act of 1980: Effects

- Other motives for university patenting:
  - Faculty pressure.
  - Economic development/technology transfer.
  - Research funding from industry, other sources.
  - “Research freedom,” especially in the absence of “experimental use” infringement defense.
- Has growth in academic patenting (reflecting many factors other than BD) impeded science?
  - Do patents on inputs slow, redirect academic research?
    - Survey evidence: academics do not search patents.
  - Increased volume, complexity of “Materials Transfer Agreements” (MTAs) covering tools, materials.
    - MTAs can constrain researchers.
  - Broader “chill” on communication among scientists?

# A “Bayh-Dole model” and Prop. 71

- BD Act is a fact of life for CA biomedical research in universities and elsewhere.
  - Future funding for CA academic biomedical research will be dominated by non-Prop. 71 sources (UC system alone received \$874M in FY 2002 from NIH).
  - If federal, non-federal SC funding both fund research, Bayh-Dole applies.
  - Federal restrictions prevent NIH funding of SC research at present; but use of similar administrative structures for SC-related IP management should reduce overhead.
- “BD model” (delegation of responsibility to research performers) exploits accumulated expertise within research performers’ TTOs.
- A CA “BD model” should support open research.

# **Prop. 71, the “BD model,” and CA economic benefits**

- Net licensing revenues from patents associated with SC research are likely to be modest.
  - Research is further upstream than most of the “public-private partnerships” supported by Gates, other foundations.
  - Commercialization of research results will require considerable time & investment.
- Benefits from Prop. 71 from economic spillovers likely to dwarf licensing revenues.
  - CA’s infrastructure for commercializing biotech inventions & the “sticky” nature of knowledge associated with this research => majority of these economic benefits will remain in-state.



# **Prop. 71 IP policies should serve “open science”**

- Reduce restrictions on transfer of materials.
  - Encourage funding recipients (including industry) to use less complex Material Transfer Agreements.
- Coordinate research exemption, “open-science” policies with other state SC programs.
  - Reciprocal research exemption for use of patents issued to CIRM, other states’ research programs?
- Support guidelines for liberal licensing of Prop. 71 patents.
  - Minimize exclusive licensing of “inputs to science” (e.g., the WARF stem-cell lines).
  - Retain BD’s “paid-up gov’t license,” “march-in rights.”
- State “clawback” of share of licensing revenue is the least cumbersome “public interest” licensing policy.
  - But state revenue yield will not be large.