

# DNA Patents: Benefits, Obstacles and Policy Options

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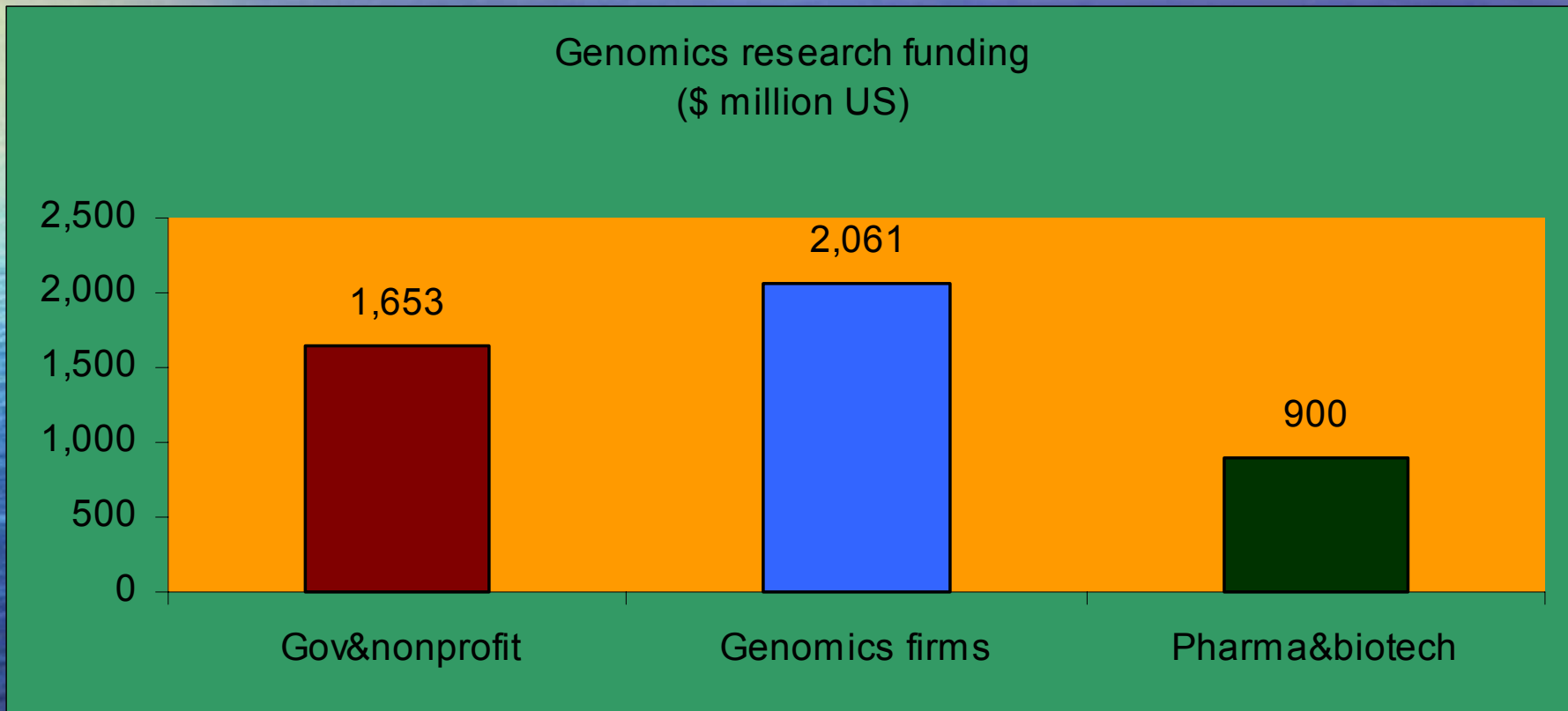
# Sources and collaborators

- DNA Patent Database  
(Georgetown University  
and Foundation for  
Genetic Medicine)
- World Survey of  
Funding for Genomics  
Research  
(Stanford-in-  
Washington)

LeRoy Walters, Steve  
McCormack, Richard  
Burgess, Janella  
Gatchalian, Miranda  
Ip, Derrick Pau, Lori  
Pressman

Amber Johnson, Carmie  
Chan, Shirley Delaleu,  
Susan Canny, David  
Kaufman

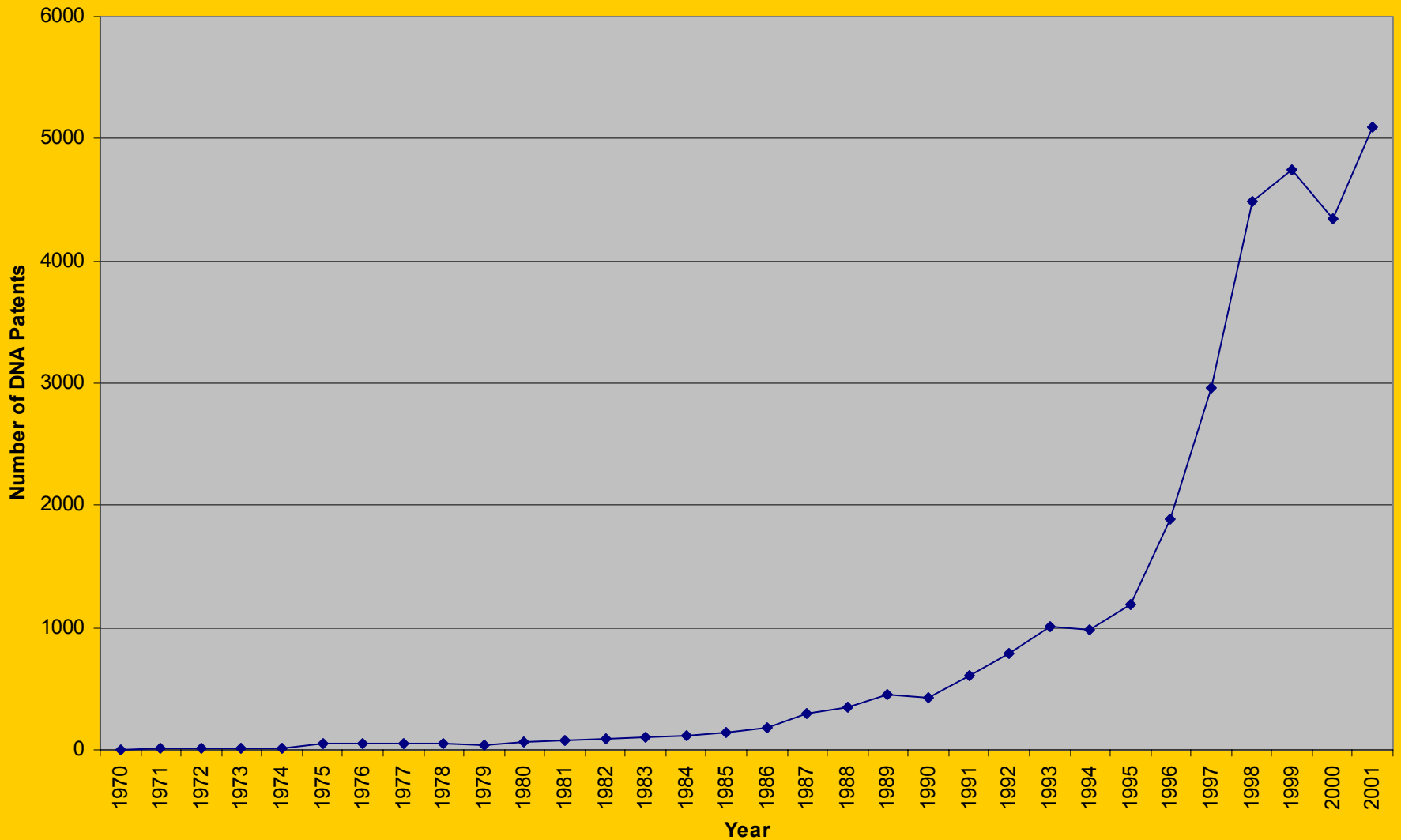
# Genomics Funding: Private > public (year 2000)



Source: World Survey of Funding for Genomics Research  
Stanford in Washington Program

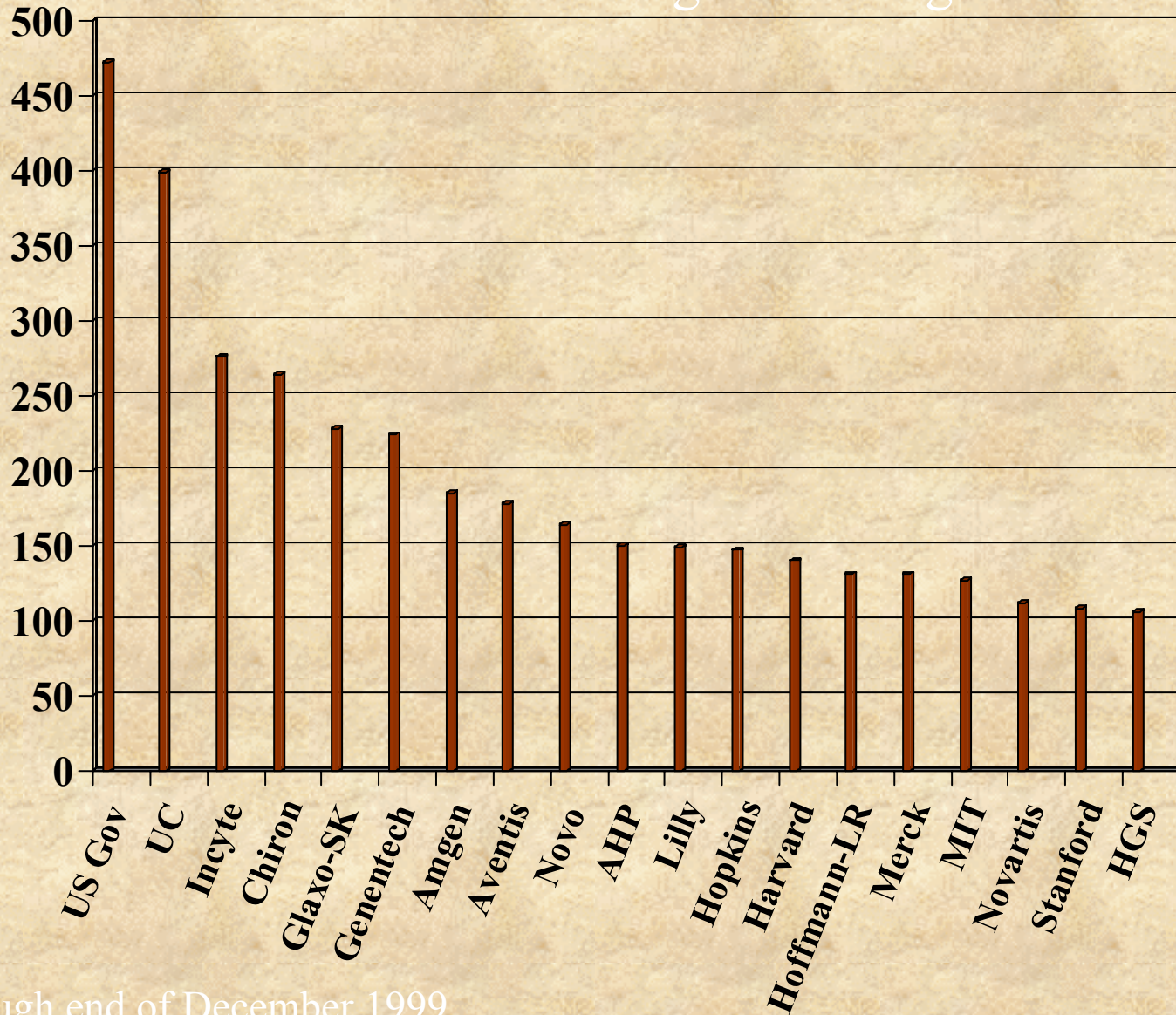
<http://www.stanford.edu/class/siw198q/websites/genomics/>

### DNA-Based U.S. Patents, 1970-2001



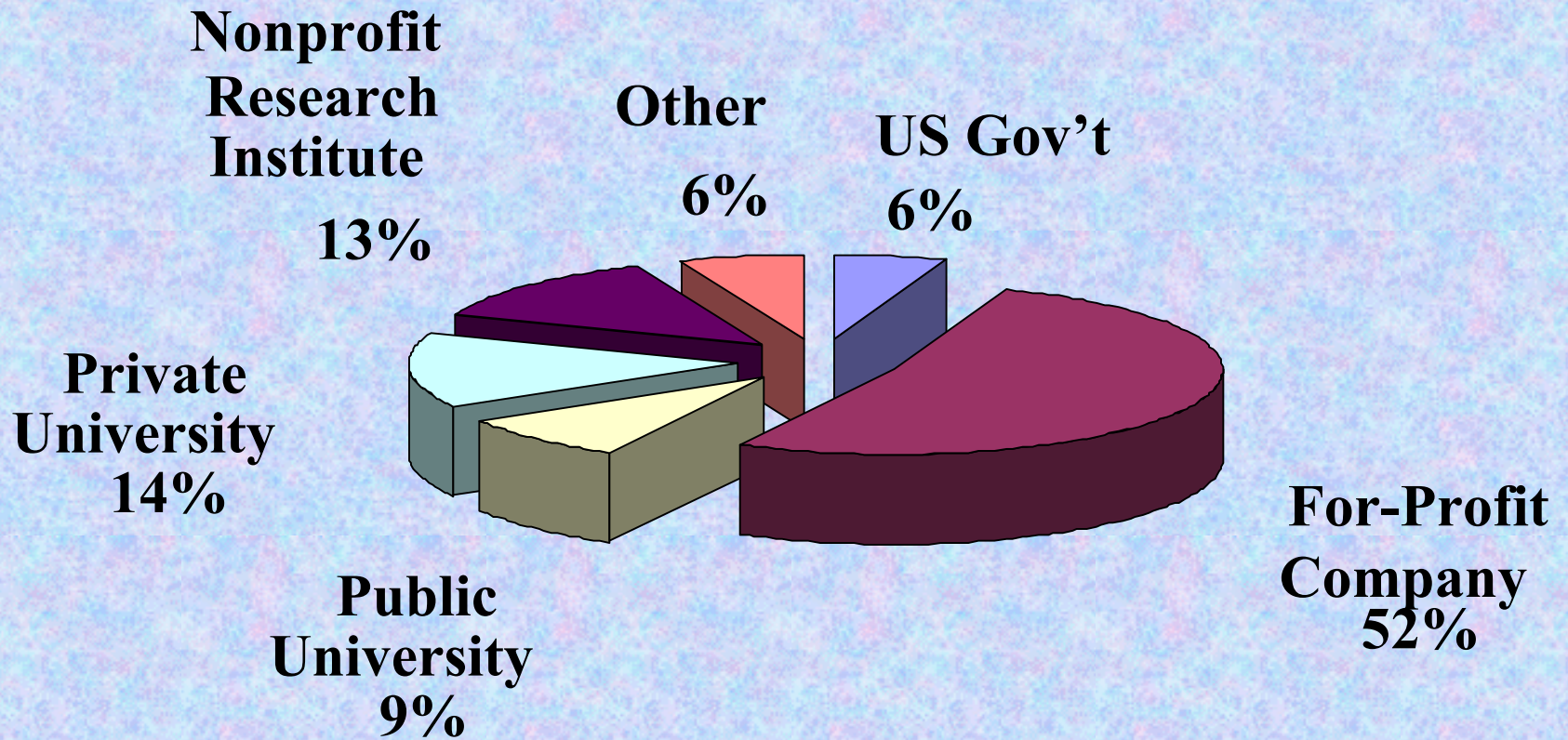
Source: LeRoy Walters, DNA Patent Database, December 2001

# Patents in DNA Patent Database 1980-1999 [www.genomic.org](http://www.genomic.org)



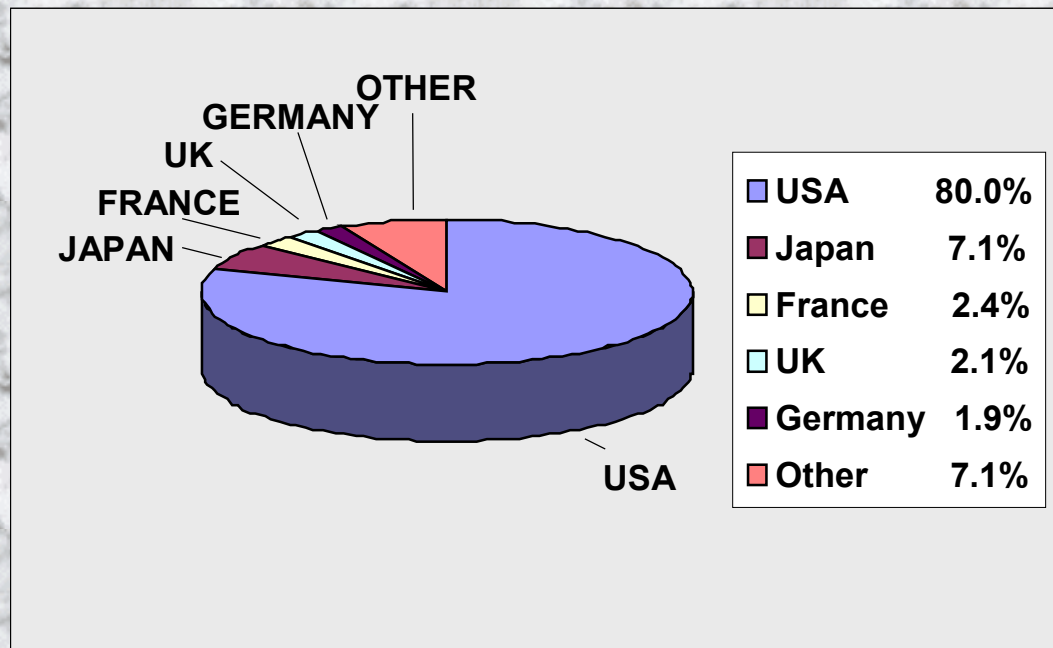
Data through end of December 1999

# Patent assignees



Source: Stephen McCormack and Robert Cook-Deegan  
DNA Patent Database [www.genomic.org](http://www.genomic.org)

# Ownership (assignee country) of DNA-based patents 1980-1993



Source: Stephen McCormack and Robert Cook-Deegan  
DNA Patent Database, August 1999, [www.genomic.org](http://www.genomic.org)

# Valuable Gene Patents

(Rosenberg patents)

- Human Insulin
- Clot-dissolving enzymes
- Growth Factors
  - Erythropoietin
  - White blood cell lineages

# Sources of value

- Clinically useful
- Scientifically valuable
- Commercially successful

# Techniques

- Cohen-Boyer rDNA
- Polymerase chain reaction
- 4-color fluorescence automated sequencing
- Multiplex sequencing
- Microarray techniques
- Gene transfer

## Boyle technologies (public domain)

- Sanger sequencing
- Maxam-Gilbert sequencing
- Monoclonal antibody production

# Diagnostics

- Huntington's by RFLP
  - Cystic Fibrosis
    - Research exemption
  - ApoE for Alzheimer's
    - Exclusively licensed
  - BrCA1 & 2
    - One company
  - Hemochromatosis
  - Many genes and mutations
- Most single nucleotide polymorphisms
  - Many genes and mutations

# Trade secrets the alternative?

- DNA sequence *\*is\** a trade secret now, when it has any value to science
  - Patent system failing to make “open” information when it is valuable and novel
- Sequences and genes a fixed set
  - Cannot stay secret with robust public domain
  - Hard to work around

# Patents induce private development investment

- Automated sequencing
- Therapeutic proteins: gene patents protect post-discovery development investment
  - long clinical trial testing period
  - Trials and manufacturing startup expensive
- Microarray applications

# Patents were not essential to induce **health research** investment

- BrCA1 & 2 and hemochromatosis
- Cohen-Boyer
- PCR
- Sequencing methods
- Cell fusion and monoclonal antibody techniques
- Most university-based discoveries

# Patents a source of revenue

- Startups (intellectual “capital”)
- Universities (licensing income)

# Bayh-Dole Act: Purpose

- Commercially exploit inventions developed using federal funds
- Legal mandate and financial incentive to do business with firms that can develop an invention into a product or service

# Policy Options: Bayh-Dole

- Transparency
  - Stop flying blind
- Research exemption
- Diagnostic use exemption
- More flexibility to pre-empt patenting
- Licensing oversight and march-in
- Earlier release of sequence data

# Policy Options: Universities

- Informational “markets” on licensing terms
- Explicit attention to where scientific and academic norms conflict with business interests and revenue-maximization
- Due diligence on licensees
- Patent pools?

# Policy options: NIH

- Guidance on disposition of research tools
- Guidance on licensing practices
- Develop criteria for “exceptional circumstances”
- Develop criteria for “march-in”
- Patent pool?

# Policy Options: Companies

- Consortia for preserving public domain research tools
  - EST
  - SNP
- Patent pools
- Guidance on licensing practices
  - BIO and PhRMA

# Policy Options: IP law

- Research exemption for all patents
  - What about academic health centers as major service providers?  
Exemption kills that market.
- Shift to “opposition” rather than “re-examination
- Data exclusivity for FDA approval as a substitute for patents (for therapeutics and devices)
- Liability rules and contract practices; unfair competition law (per Reichman/Uhlir)
- Database protection