A banner for the California's Stem Cell Initiative. It features a background image of petri dishes with blue liquid. Overlaid on the left are three white circles of varying sizes, with dashed lines connecting them. The text "(stem cell research)" is in green, lowercase letters inside the smallest circle.

(stem cell research)

CALIFORNIA'S STEM CELL INITIATIVE

CONFRONTING THE LEGAL & POLICY CHALLENGES

March 2 - 4, 2006

Getting IP Rights Right

Prof. Robert P. Merges

Boalt Hall

3.3.2006

Primary Issues

- **Historical Overview: Ethical considerations and US Patent Law**
- **Brief Review of major IP issues related to California Stem Cell Initiative**
- **Specific recommendations**
 - **“Some strings attached” approach**

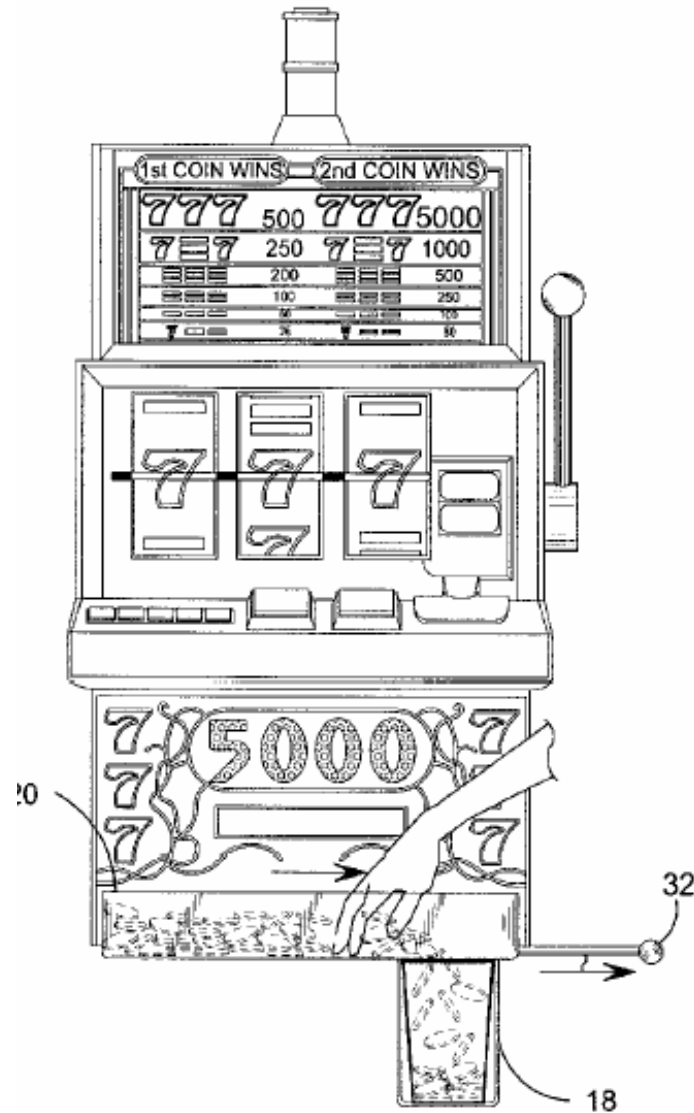
Historical Overview

- **Moral and ethical considerations enter into patent law decisionmaking in only *a very limited way***

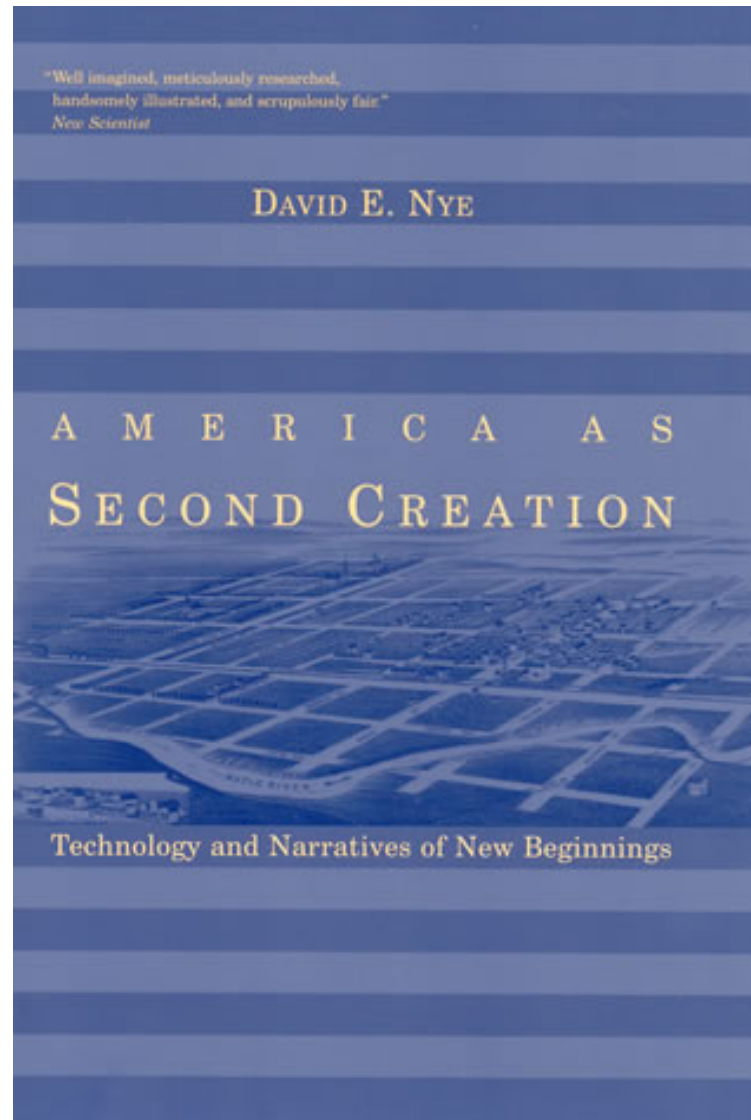
“Division of labor” theory

- **Merges, The Patentability of Higher Life Forms: Intellectual Property Rights and Controversial Technologies, 47 *Maryland Law Review* 1051-1075 (1988).**

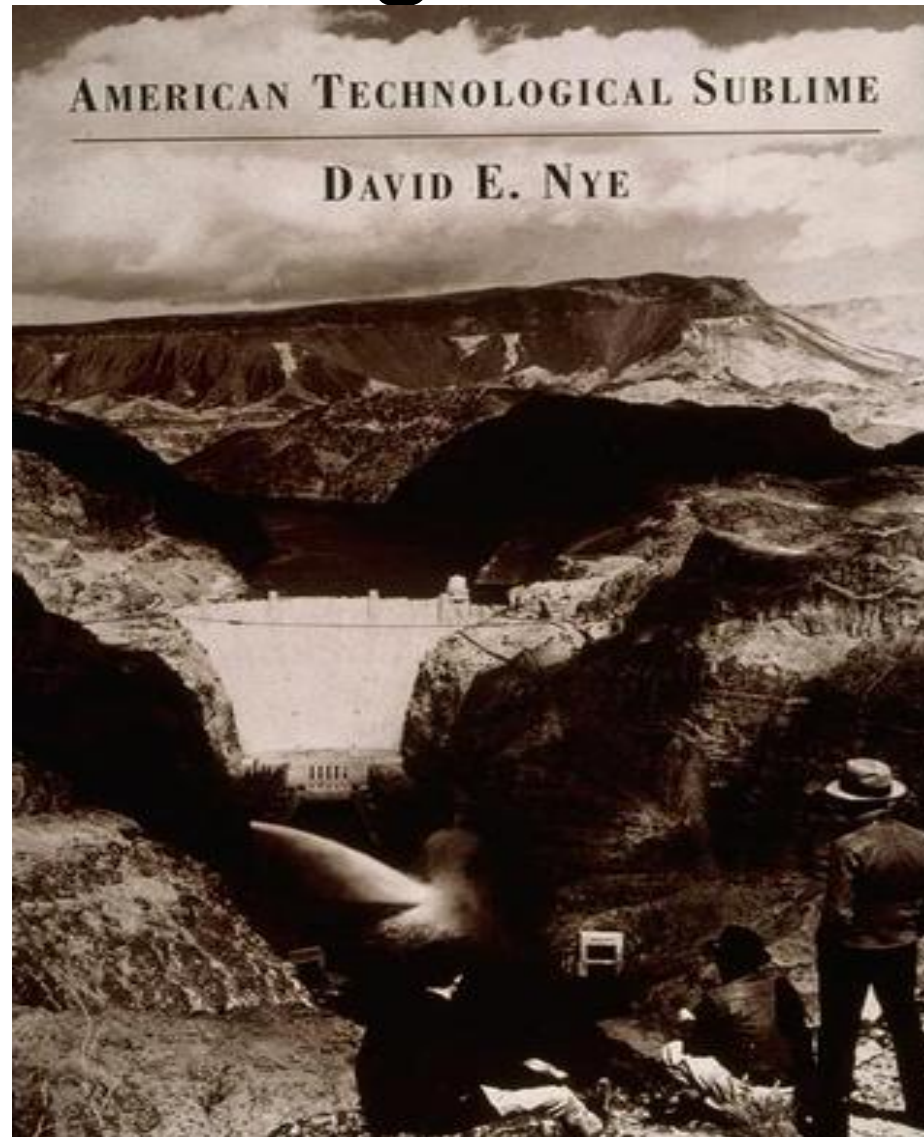
Case Study: Gambling Patents



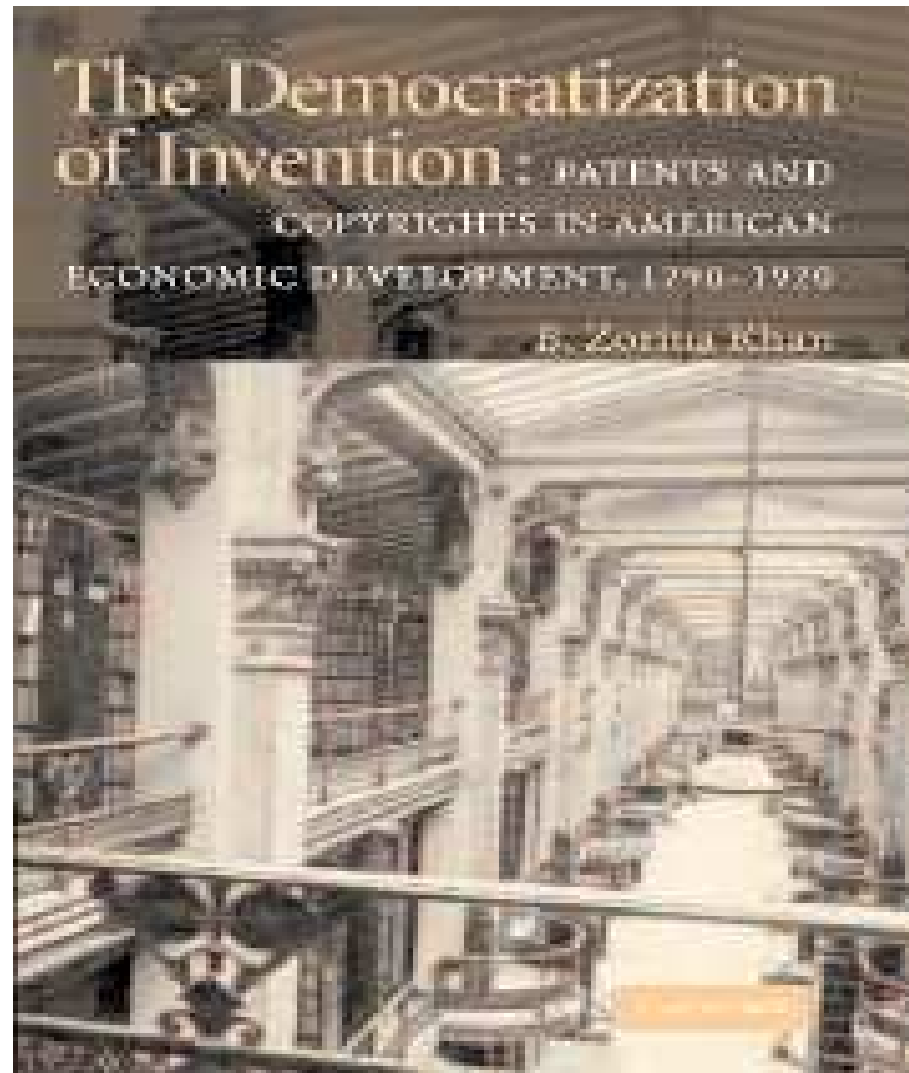
David Nye, *America as Second Creation* (2003)



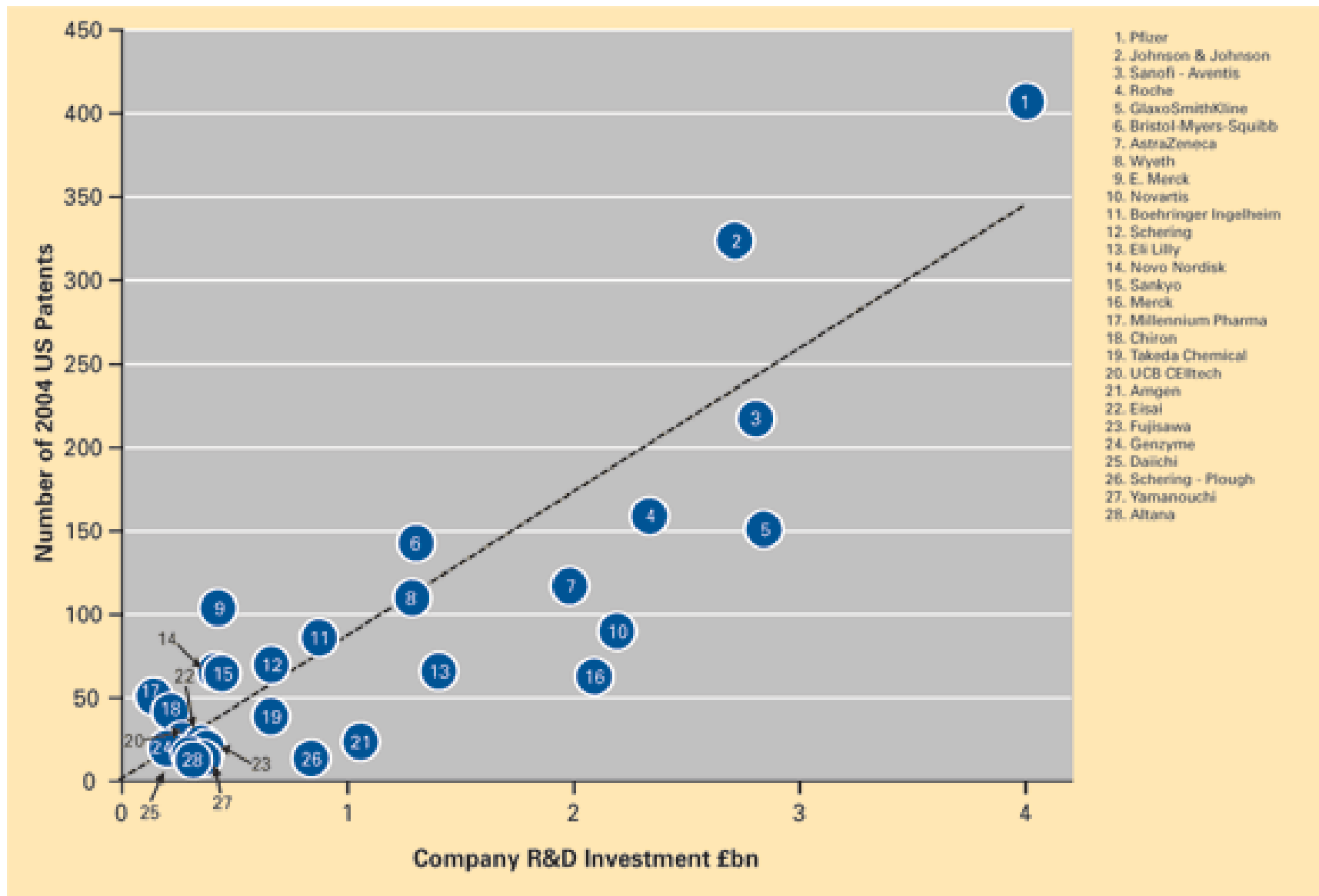
David Nye, American Technological Sublime



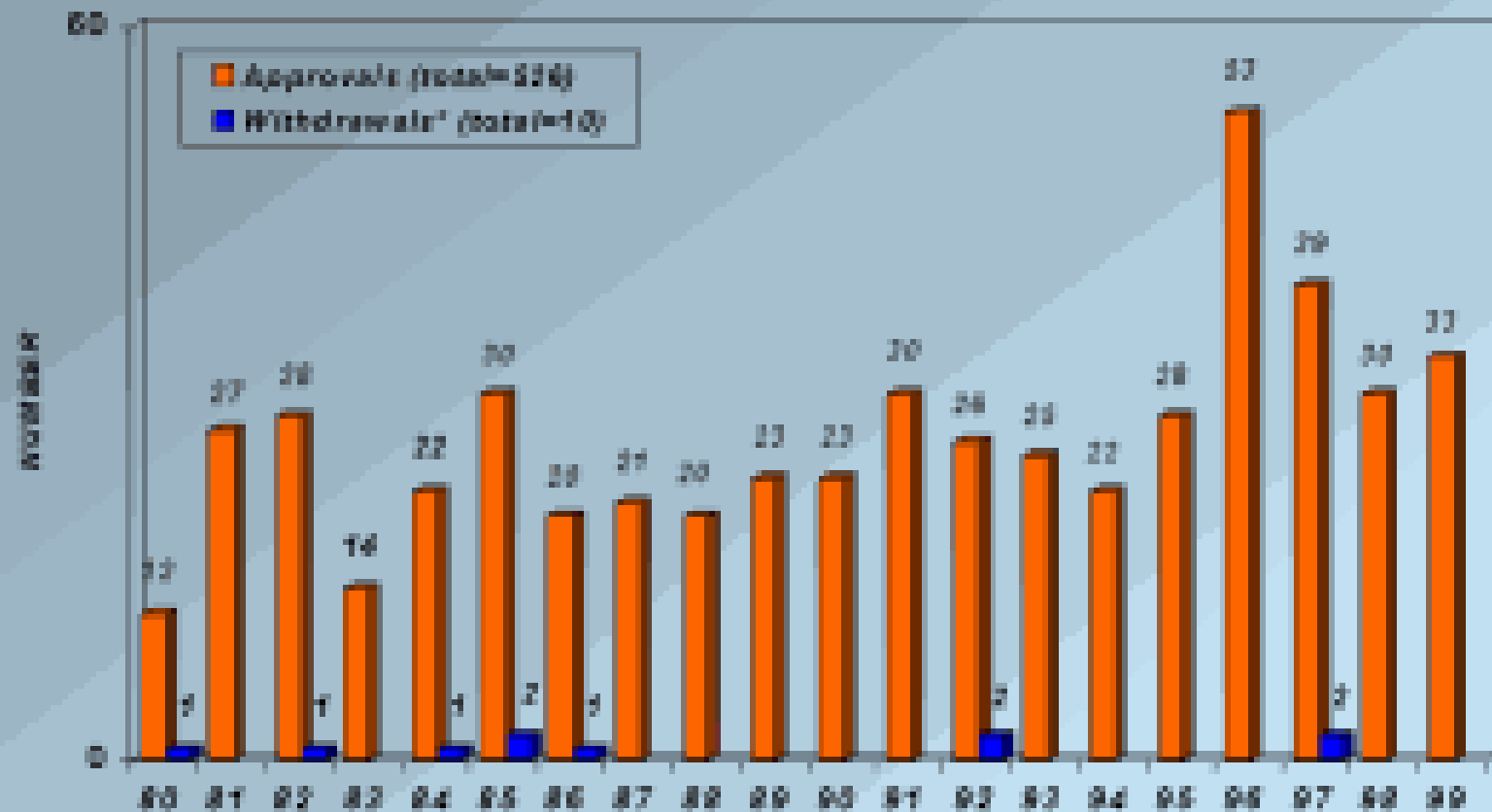
Zorina Khan, The Democratization of Invention



Patents and R&D Investment



New Drug Approvals and Withdrawals 1990-1999



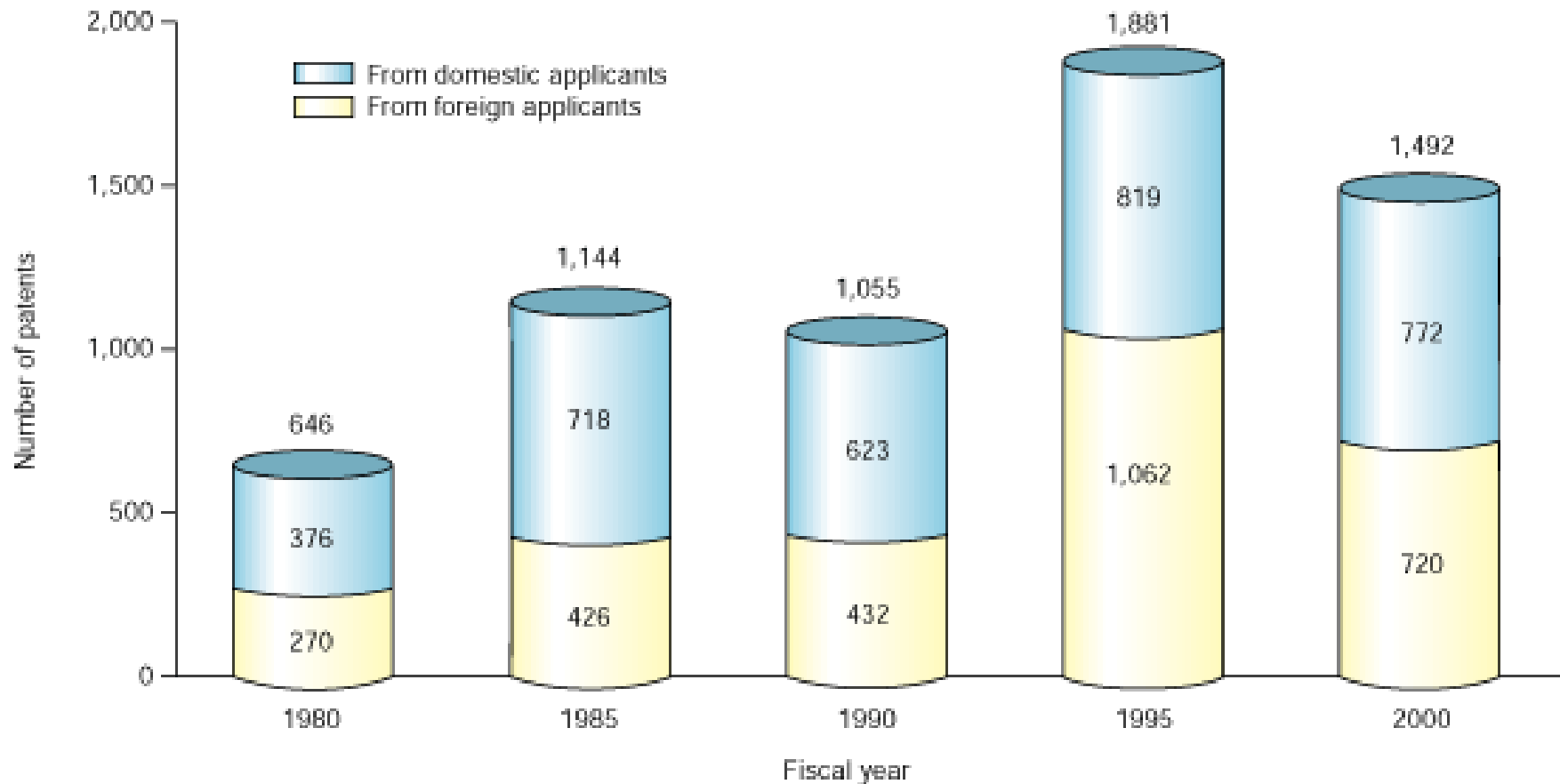
* Withdrawals indicated by year of drug approval

Source: Tufts CSDD, 2009

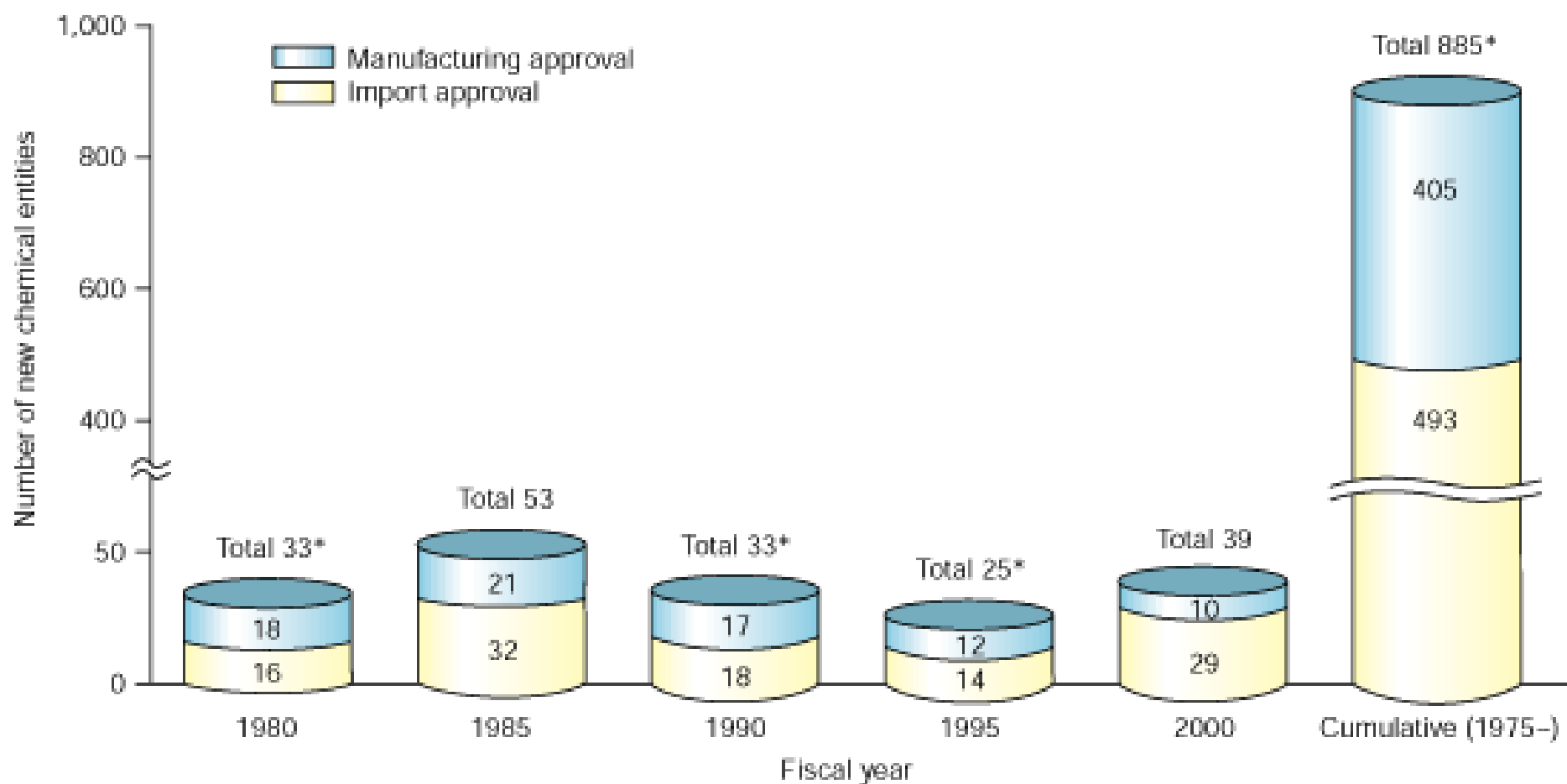
Tufts CSDD



Many patents . . .



Very few product approvals



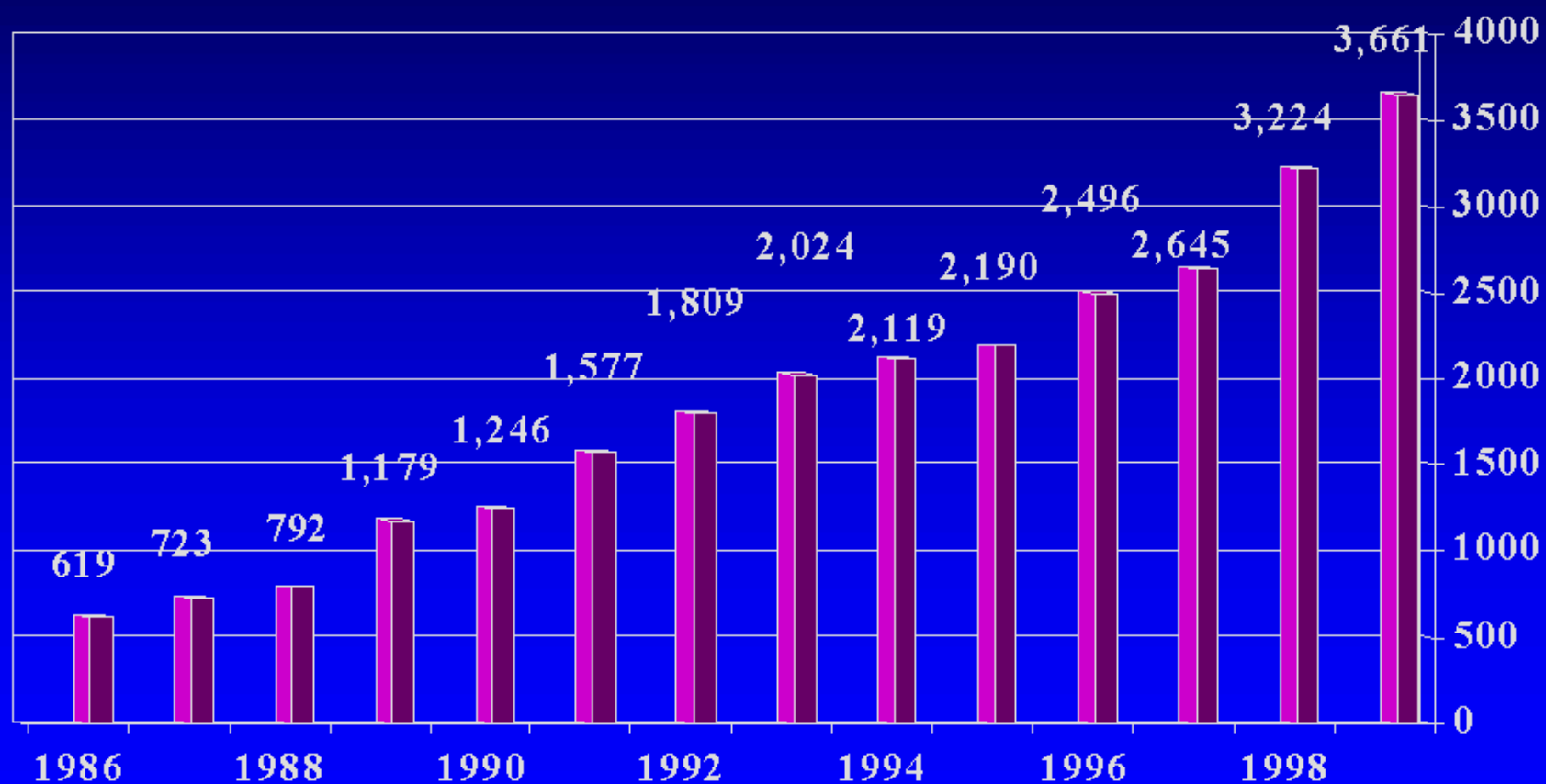
Paul A. David - Stanford



**“Can ‘Open
Science’ be
Protected
from the
Evolving
Regime of IPR
Protections?”**



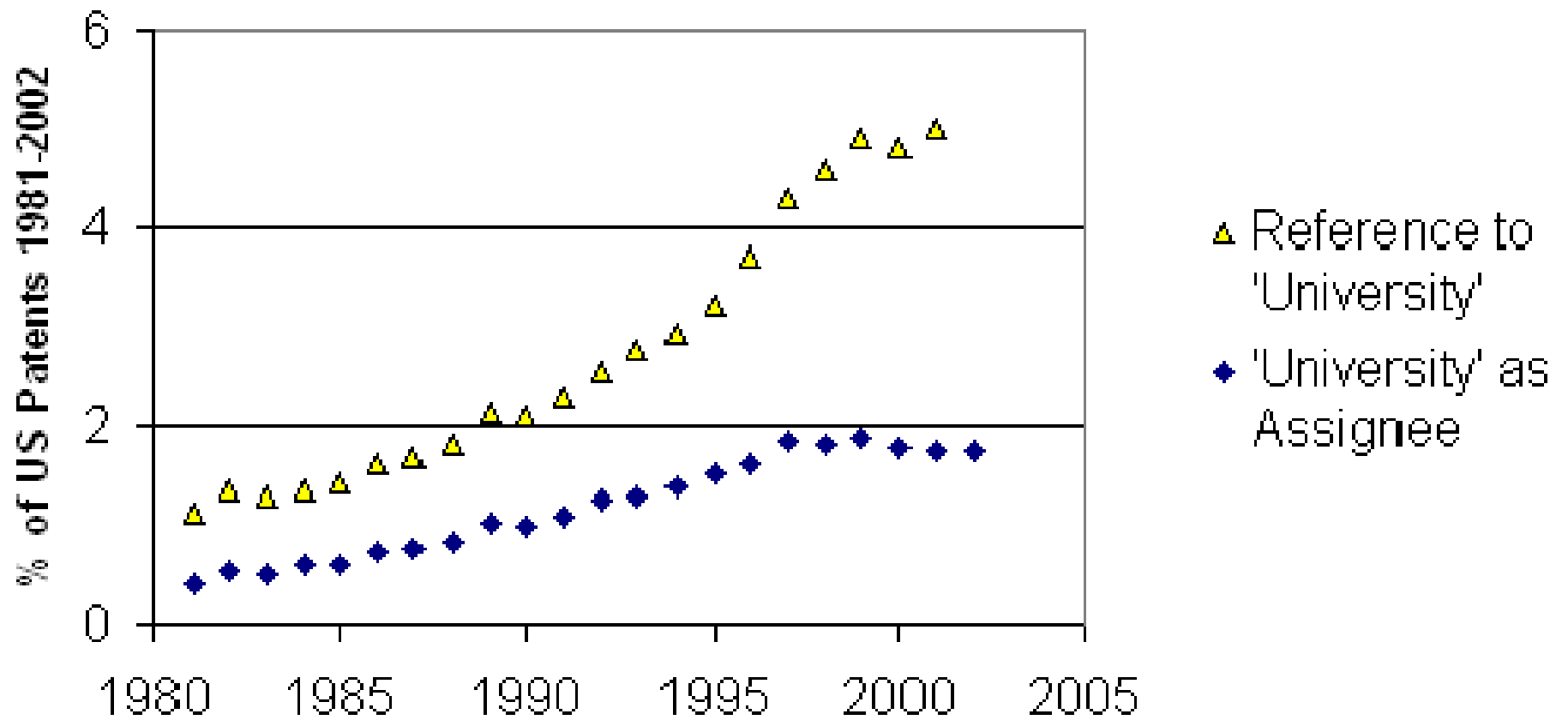
Patents to Universities 1986 - 1999



David Mowery et al.



- “Ivory Tower and Industrial Innovation: *University-Industry Technology Transfer Before and After the Bayh-Dole Act*”
- 2004



Loet Leydesdorff, University of Amsterdam

- **Lori Pressman, et al., *The Licensing of DNA Patents by U.S. Institutions*, 24 Nature Biotech. 31-39 (1 Jan. 2006)**
 - **University licensing offices do a good job balancing economic goals with social goals, “such as ensuring utilization and availability of federally funded inventions.”**
- p. 39**

Exclusivity in limited fields, to promote maximum usage of inventions

Milestones and termination provisions to ensure diligence by licensees

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Eric G. Campbell *et al.*, **Data Withholding
in Academic Genetics: Evidence from a
National Survey.** *Journal of the American
Medical Association* 287 (4):473 – 479
(2002)

35% of respondents said secrecy a bigger
problem in 1990 vs. 1980; 58% said data
withholding hurt their research

- **Jeremy M. Grushcow, *Measuring Secrecy: A Cost of the Patent System Revealed*, 33 J. Legal Stud. 59 (2004)**
- **John P. Walsh & Wei Hong, *Secrecy is Increasing in Step with Competition*, 422 Nature 801 (2003).**

Recommendations: “Some Strings Attached”

- **Encourage private commercialization via licensing**
- **Require limited exclusivity, where relevant, milestones and termination provisions**
- **Discourage publication delays**