

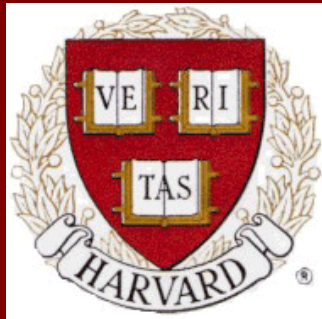
Managing Intellectual Property in
Academia to Ensure Future
Access to Products

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Once Upon a Time...

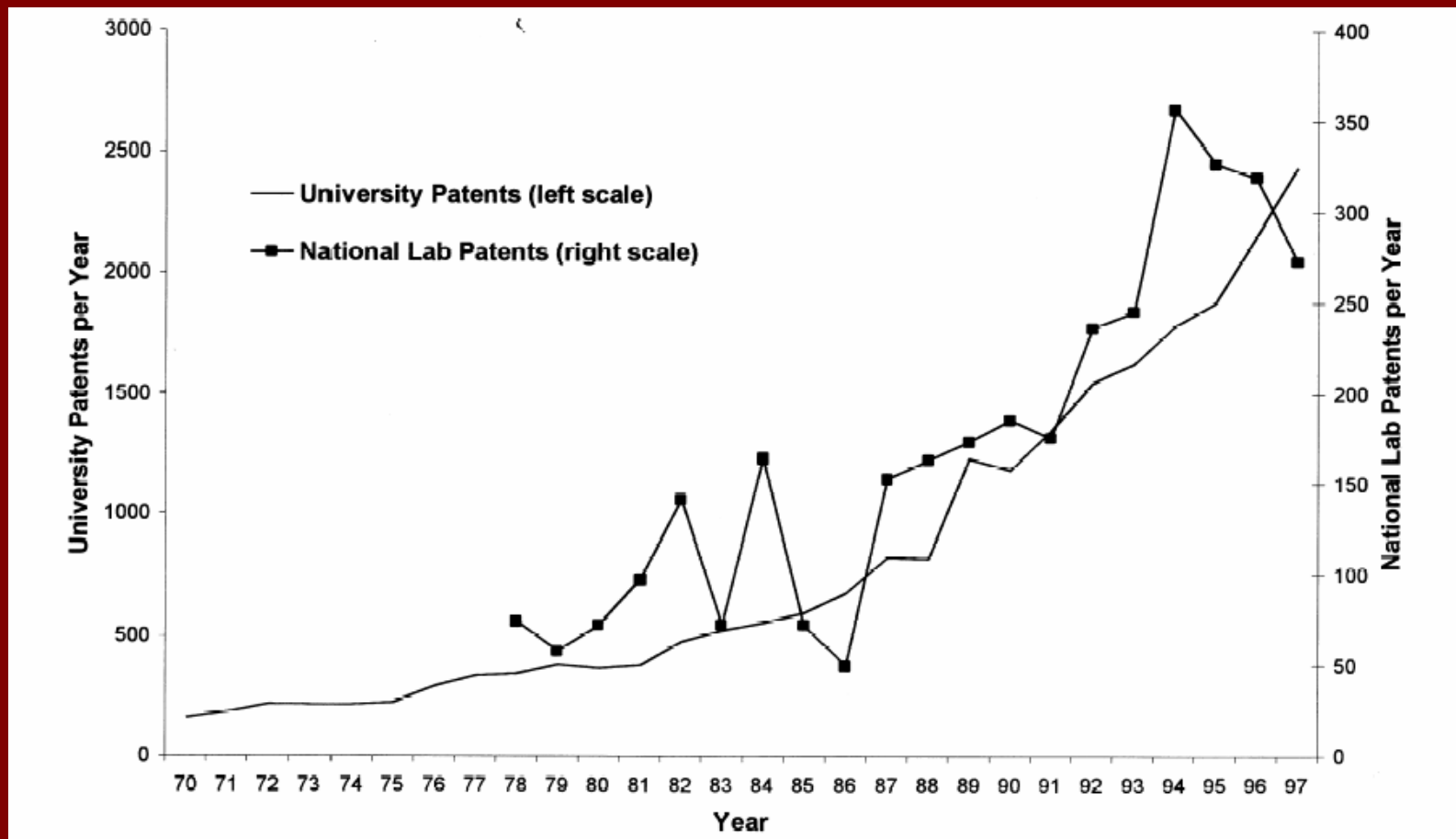


— “No patents primarily concerned with therapeutics or public health may be taken out by any member of the University, except with the consent of the President and Fellows; nor will such patents be taken out by the University itself except for dedication to the public.”

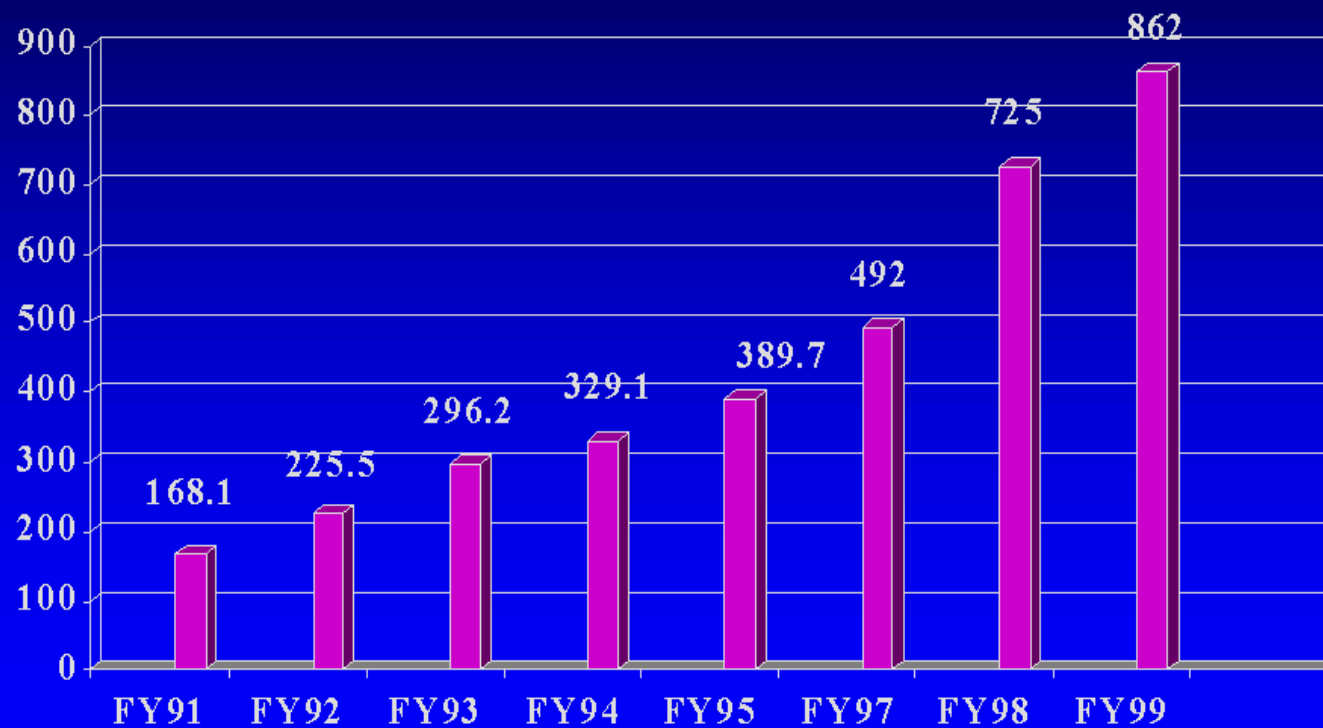
“it is, in general, undesirable and contrary to the best interests of medicine and the public to patent any discovery or invention applicable in the fields of public health or medicine”



Through the Looking Glass



A Mad Tea-Party?



Royalties to Universities/Hospitals in Millions of Dollars

Source: Bremer, 2001 speech (<http://www.autm.net>) - data from AUTM Licensing Survey

Legal Framework: Bayh-Dole Act (1980)

- Universities given right to take out patents in inventions created through federal research grants
- Exclusive licensing also permitted
- Government retains (theoretical) “march-in” rights

Rationale for Bayh-Dole

Commercialization: Basic nature of university research requires further development by industry

Incentive: Encourage universities to transfer technology

But what if

- The invention doesn't require further development (i.e. research tools)?
- The partner is a public sector institution or non-profit?
- In both cases, there is no justification and likely no benefit of a patent (but Bayh-Dole permits it)

Problems

Patenting and licensing practices sometimes impede research (SIPPI study of AAAS member)

- 40% of university and industry respondents reported difficulties getting access to patented material for research
- 35% of academic respondents who reported difficulties said it affected their research (58% said it delayed it, 50% said they had to change their research, and 28% said they had to abandon their research)

University tech transfer offices have been slow to address access issues in low and middle income countries

- In 2000, Yale's patented d4T cost \$1600 per patient per year in South Africa. Generic versions cost more than 95% less, but were illegal to import because of Yale's patent.

Current Practices

Research Tools

- Some left in public domain
- Some exclusively licensed, (but rights often retained for university researchers)
- Many are non-exclusively licensed, for a fee
- *Rarely*, licensed in self-sustaining research commons (e.g. WARF stem cell)

Drug Candidates

- Most exclusively licensed to biotech or pharma
- A few licensed to PPPs, non-profits, etc.
- *Rarely*, access agreement negotiated

RECENT DEVELOPMENTS

- **Sept 2006** S. 4040 (Leahy Bill)
- **Nov 2006** Philadelphia Consensus Statement
 - Universities should*
 - Require licensing terms to ensure access in LMI countries
 - Develop strategies to ensure access where open licensing is not appropriate
 - Promote R&D for neglected diseases
 - Measure success according to impact on human welfare
- **Dec 2006** U of Washington adopts “access first”
licensing policy

Commons-Based Solutions

- Universities and public sector institutions should adopt access-first patenting and licensing policies
 - No patents on TB research tools (and consider self-sustaining research commons or pool)
 - For drugs and diagnostics, negotiate with partners to ensure low-cost access to resulting products in target countries. Goal: free competition, or no-profit pricing
- Sign the Philadelphia Consensus Statement
 - <http://www.essentialmedicine.org>
- Urge your university to adopt an access-first policy