The Bayh-Dole Act – History and Impact

Dr. Ashley J. Stevens
Lecturer
Strategy and Innovation Department
School of Management

Boston University

Objectives

Give you:

- A sense of the role of universities in the innovation economy
- An understanding of how the process works
- A feeling for some of the unique issues associated with licensing from universities

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Who Owns the Results of Federally Funded Research?

- Normally, he who pays the piper calls the tune
- Government funds the overwhelming bulk of university research
- Used to own the resultant IP
- Was totally ineffective at utilizing the IP it owned

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The 1920's - 50's

- Industry was the primary source of biomedical research funding
- Relations between academia and industry were excellent
- Academia was the source of much of the technology that shaped the US pharmaceutical industry
  - Toronto — Insulin
  - Wisconsin — vitamin D, warfarin
  - Rutgers — streptomycin, neomycin
  - Oxford, USDA, MIT — penicillin
  - Sydney Farber — aminopterin, methotrexate
  - Worcester Foundation, BCH — the Pill

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Some Universities Got Into Licensing Early

Research Corporation	1917
WARF	1926
Iowa State	1935
MIT	1940
Kansas State	1942
University of Minnesota	1957

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The 1960's and 70's

- Something went wrong
- Kennedy Administration issued strong statement on patent policy and started aggressively claiming title to patents, subsequently reiterated by Nixon administration
- Three bad cases in 1965-1968 timeframe
  - PKU test
  - Gatorade
  - 5FU
- By 1968, no drug that the Government owned title to had ever been commercialized
- Senator Russell Long, (*D., LA)* particularly opposed to commercialization of university research

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The 1960's and 70's

- By 1978, Government owned title to 28,000 patents and had licensed fewer than 4% of them
  - Included royalty-free licenses
  - Professor licensing his own inventions
- Inventions reported to the Government were declining, despite booming funding of NIH and NSF
- Research was regarded as "contaminated" or "tainted" if it had received federal funding

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The 1960's and 70's

- Commercialization was 20x more likely if government waived title to the contractor
  - NASA had received 31,357 invention disclosures
    - Licensed less than 1%
  - Waived title to 1,254 cases to contractor
    - 18-20% commercialized

What Was the Problem?

- Government wouldn't grant exclusive licenses
- Bureaucratization
  - Every agency had its own policy
  - Determinations of release to contractor took 2-3 years
  - Contractor had to pay costs without any assurance of receiving title
- Separation of Inventor from Invention
  - Academic inventions are embryonic and need active involvement of the inventor
    - Government controlled the patent rights
    - University controlled access to the inventor

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IPA's – the first glimmering of a solution

(and you thought it was just an English beer)

- Initiated by Norman Latker at DHEW in 1963
- Allowed institution to own title if they agreed to staff an OTT
  - Every agency had its own policy
  - Determinations of release to contractor took 2-3 years
  - Contractor had to pay costs without any assurance of receiving title
- University of Wisconsin received first IPA's
  - DHEW in 1968
  - NSF in 1973
- 75 IPA's in place by 1976
- U. of California and Stanford allowed to administer Cohen-Boyer under their IPA's

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1978-79

"Misery Index," double-digit inflation, double-digit unemployment

End of the American Dream? Japan as #1

Innovation Crisis

Innovation Crisis

Midwest Rustbelt

Energy Crisis: Freezing in the Dark?

Chrysler Bailout

Iran Seizes Hostages

USSR Invades Afghanistan

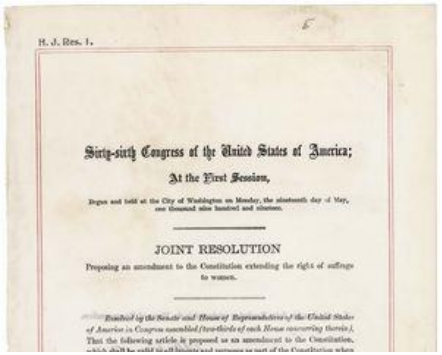
U.S. Imposes Grain Embargo; Boycotts Olympics

Debacle in the Desert: Carter Rescue Attempt Fails

At least Congress could do something about innovation

Origins of Bayh-Dole

- IPA process halted in 1977
  - Increasing cost of healthcare attributed to new technology
  - Senator Gaylord Nelson *(D., WI)* held hearings into legality of IPA's
- University of Wisconsin, Stanford, University of California and Purdue initiated move to legislate the continuance and expansion to other agencies
- Senators Birch Bayh *(D., IN)* and Robert Dole *(R., KS)* initiated legislation
- At odds with Carter Administrations plan to use academic research as part of an industrial policy to boost US competitiveness – The Stevenson-Wydler Act
- Finally passed in lame duck session in November 1980
  - Russell Long's farewell gift to Birch Bayh



TITLE IX

NO PERSON IN THE UNITED STATES SHALL, ON THE BASIS OF SEX, BE EXCLUDED FROM PARTICIPATION IN, BE DENIED THE BENEFITS OF, OR BE SUBJECTED TO DISCRIMINATION UNDER ANY EDUCATION PROGRAM OR ACTIVITY RECEIVING FEDERAL FINANCIAL ASSISTANCE.

Bayh-Dole

- PL 96-517 – The Patent and Trademark Amendments Act of 1980
- Main components:
  - Universities could elect to retain title to the results of Federally funded research
  - Universities were required to share proceeds with inventors
  - Most restrictions on licensing terms were removed
  - US manufacture required for products to be sold in the US
  - Small business preference
  - Non-exclusive license to US Government for its own use
  - Ability to grant compulsory license in the public interest
- No funding added or removed
- Remaining licensing restrictions were eliminated in the Stevenson-Wydler Act (PL98-642) in 1984

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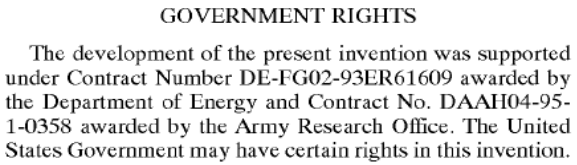
Obligations to Government

Inventor must:

- Disclose inventions to the institution

Institution must

- Report invention to funding agency
- Elect to retain title
- Grant Government a non-exclusive, non-transferable royalty-free license for its own use
- Acknowledge Government funding in the patent application



GOVERNMENT RIGHTS

The development of the present invention was supported under Contract Number DE-FG02-93ER61609 awarded by the Department of Energy and Contract No. DAAH04-95-1-0358 awarded by the Army Research Office. The United States Government may have certain rights in this invention.

- Report on utilization of the invention
- List patents in grant renewals
- Give notice before abandoning patents

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Impact

- It worked:
  - Expansion of academic licensing offices
    - Initially staffed by patent attorneys and research administrators
    - Second wave was people with small company business experience
      - The only reason to protect technology is in order to transfer it!
  - Expansion of academic patent applications and issuances
  - Substantial research collaborations between companies and universities to access new technologies
  - Substantial growth in academic royalty income about a decade later
  - Emergence of high technology clusters anchored by major research universities

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Academic Technology Transfer Activity – 2012

- 23,741 invention disclosures
- 22,1505 patent applications filed
- 14,224 new patent applications filed
- 5,145 patents issued
- 6,372 new options/licenses executed
- 40,007 licenses/options active
- 18,295 generating some sort of income
- 9,640 generating running royalties
- 224 generating >$1 million
- 705 spin-out companies

Source: Association of University Technology Managers

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Economic Impact 1996-2007*

- 279,000 jobs created
- $187 billion to added to U.S. GDP

* Roessner, J. Bond, S. Okubo, M. Planting, *The Economic Impact of Licensed Commercialized Inventions Resulting from University Research, 1996-2007* Final Report presented to the Biotechnology Industry Organization, September 9, 2009

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Economic Impact – AUTM Data

- Since 2011, have asked universities to report sales of licensed products reported by licensees
  - Information is available on royalty reports
- Compliance is relatively low
  - ~35% response rate
- Questions that allow extrapolation to full survey
  - Number of licenses generating running royalties
  - Income from running royalties
- Estimated total product sales is ~$100 billion

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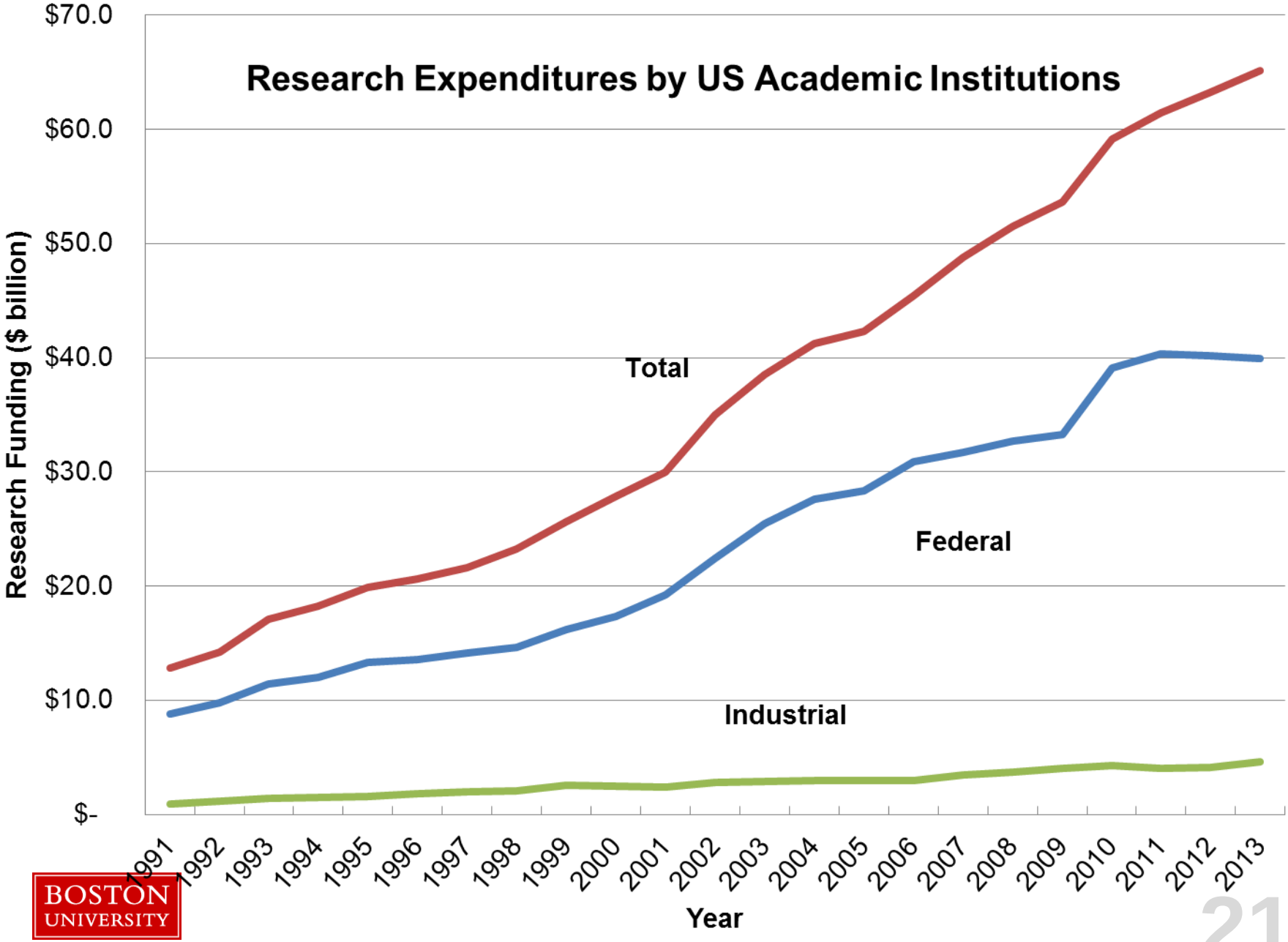

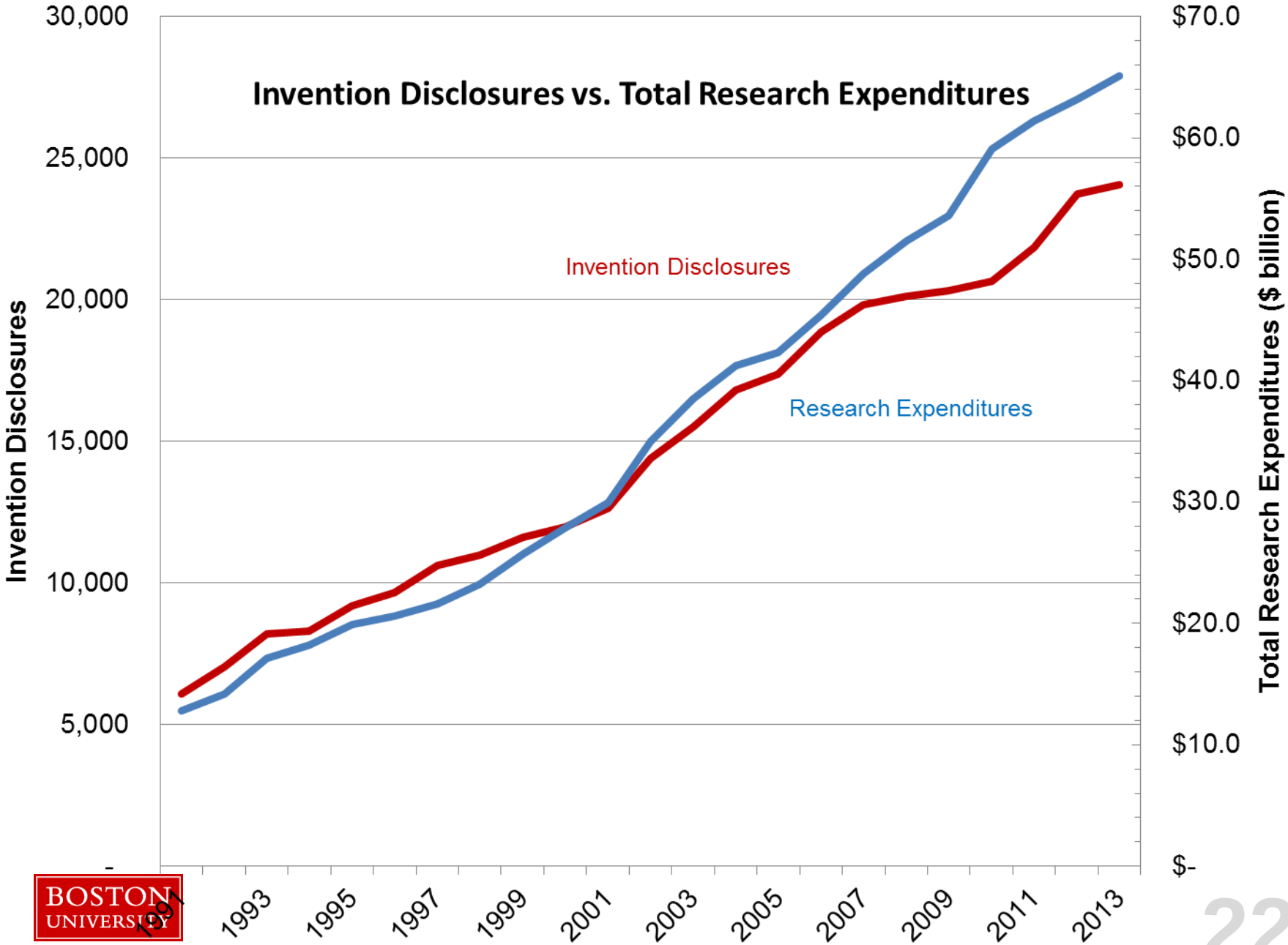

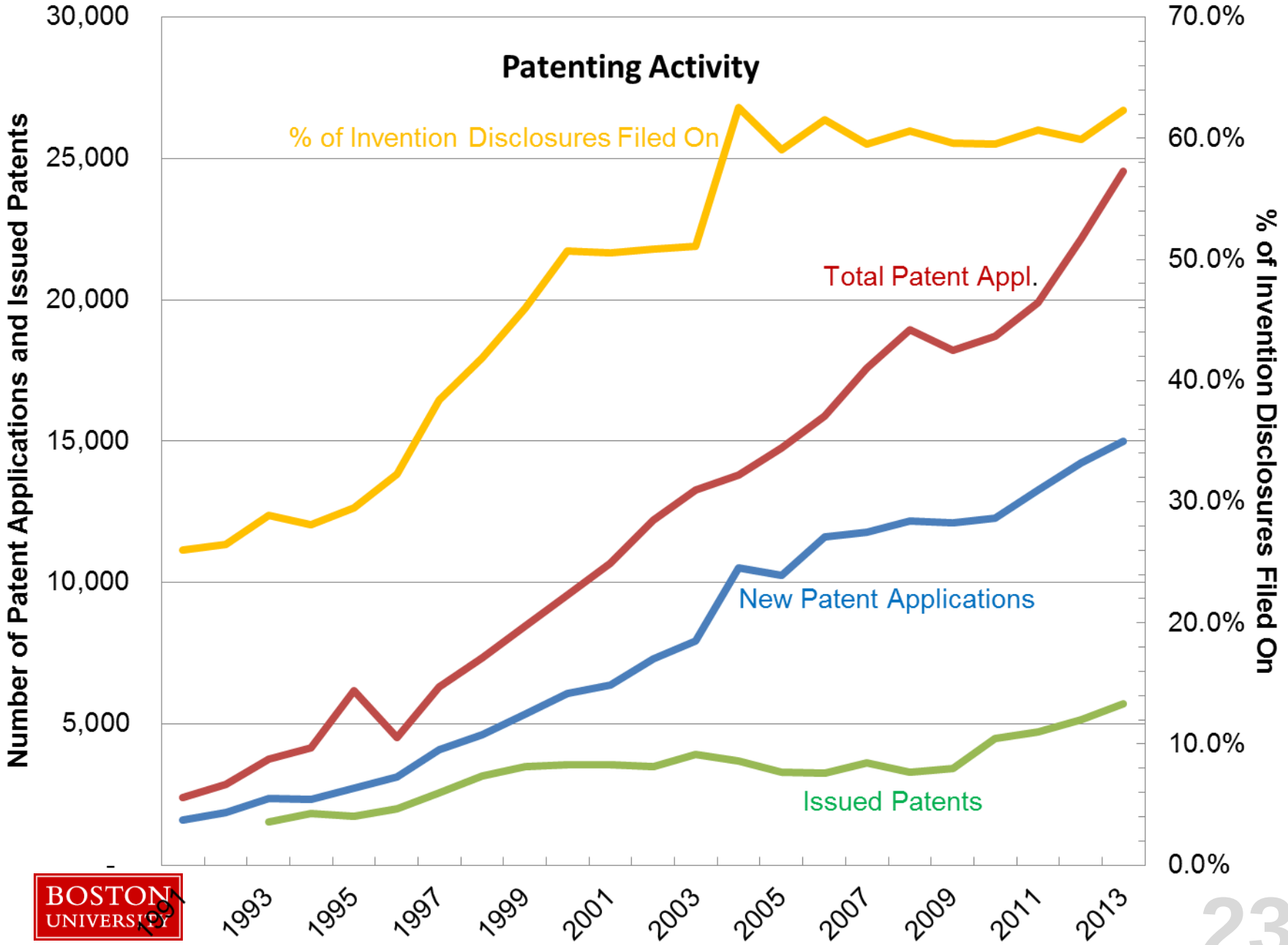

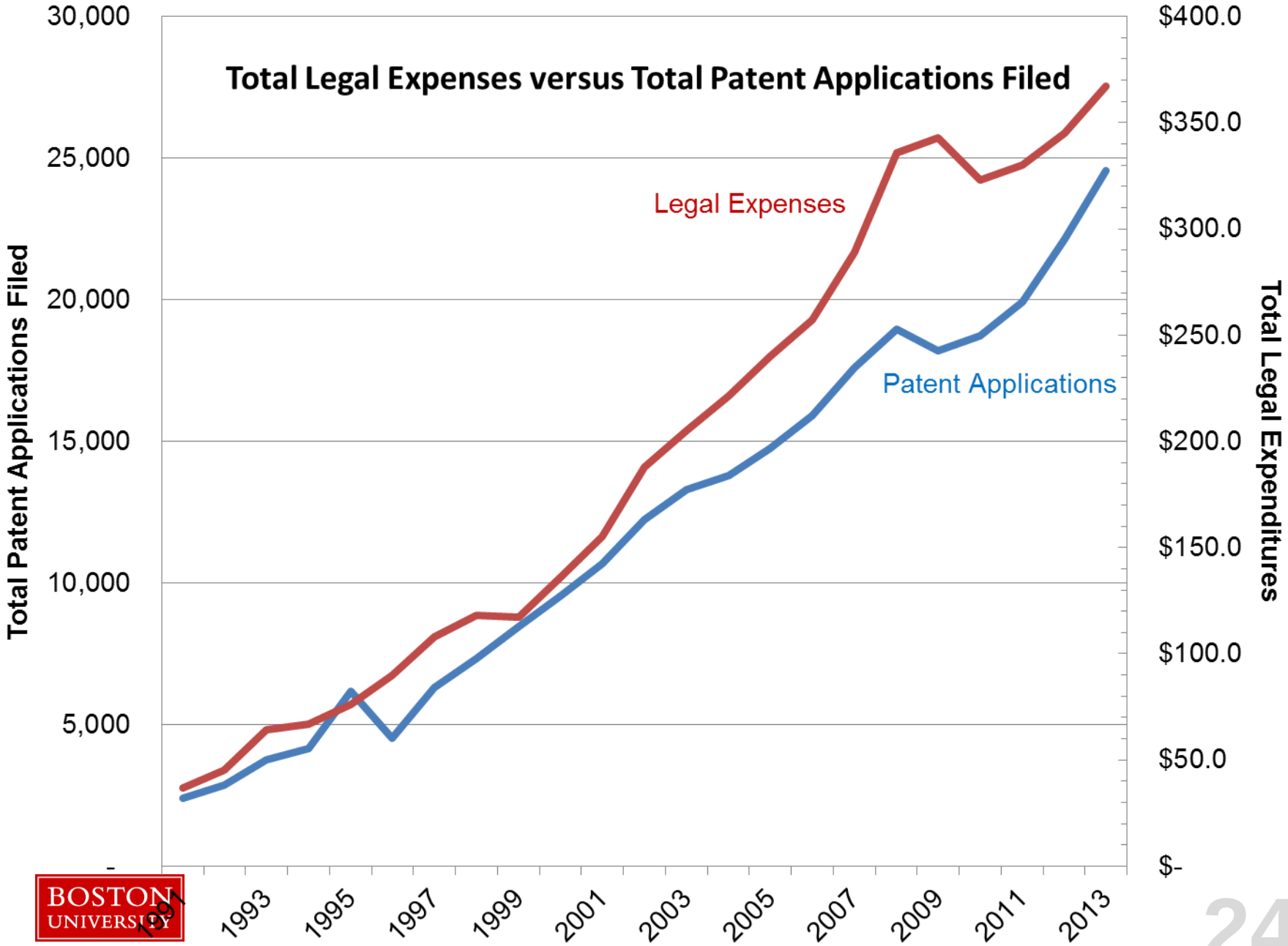

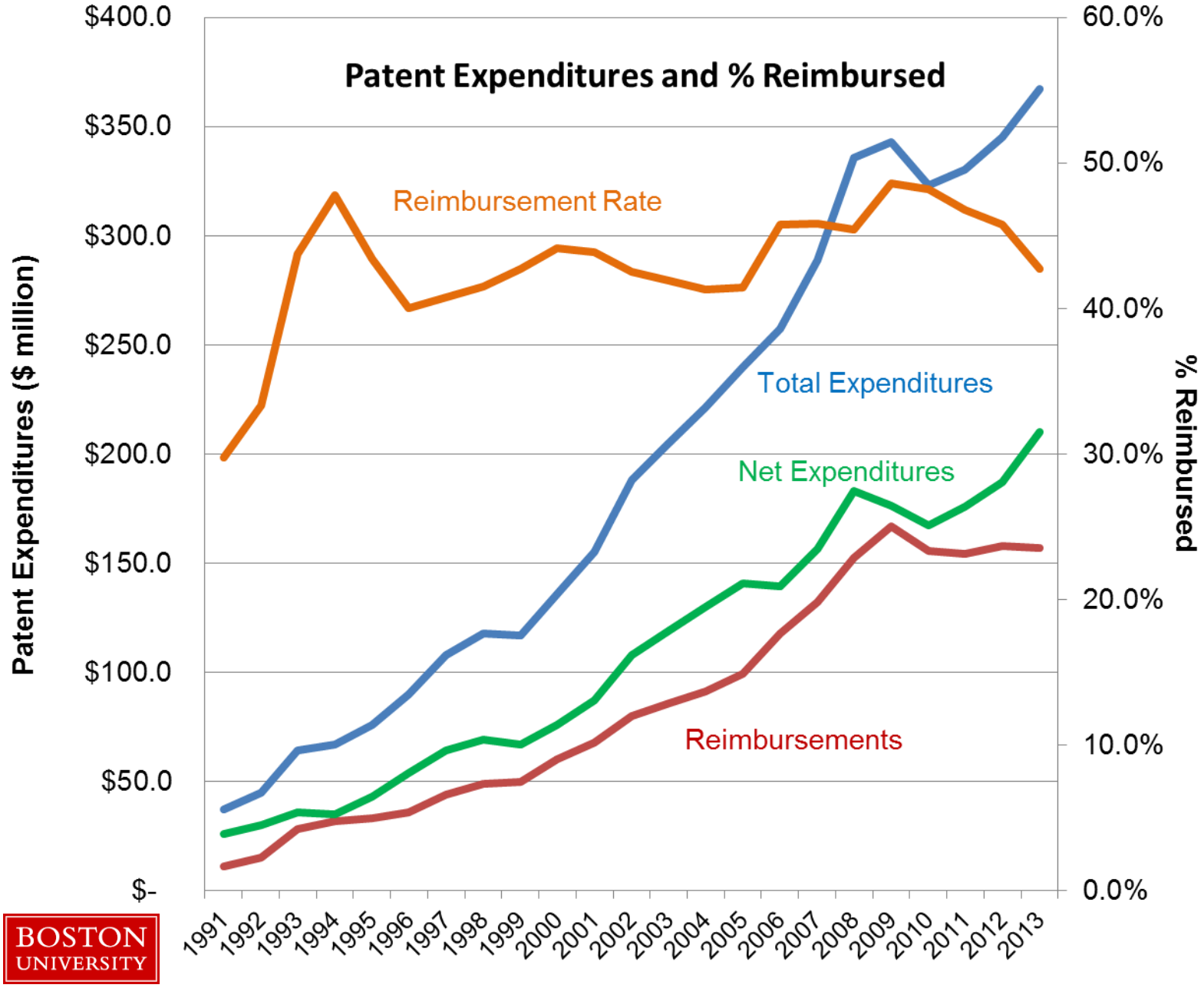

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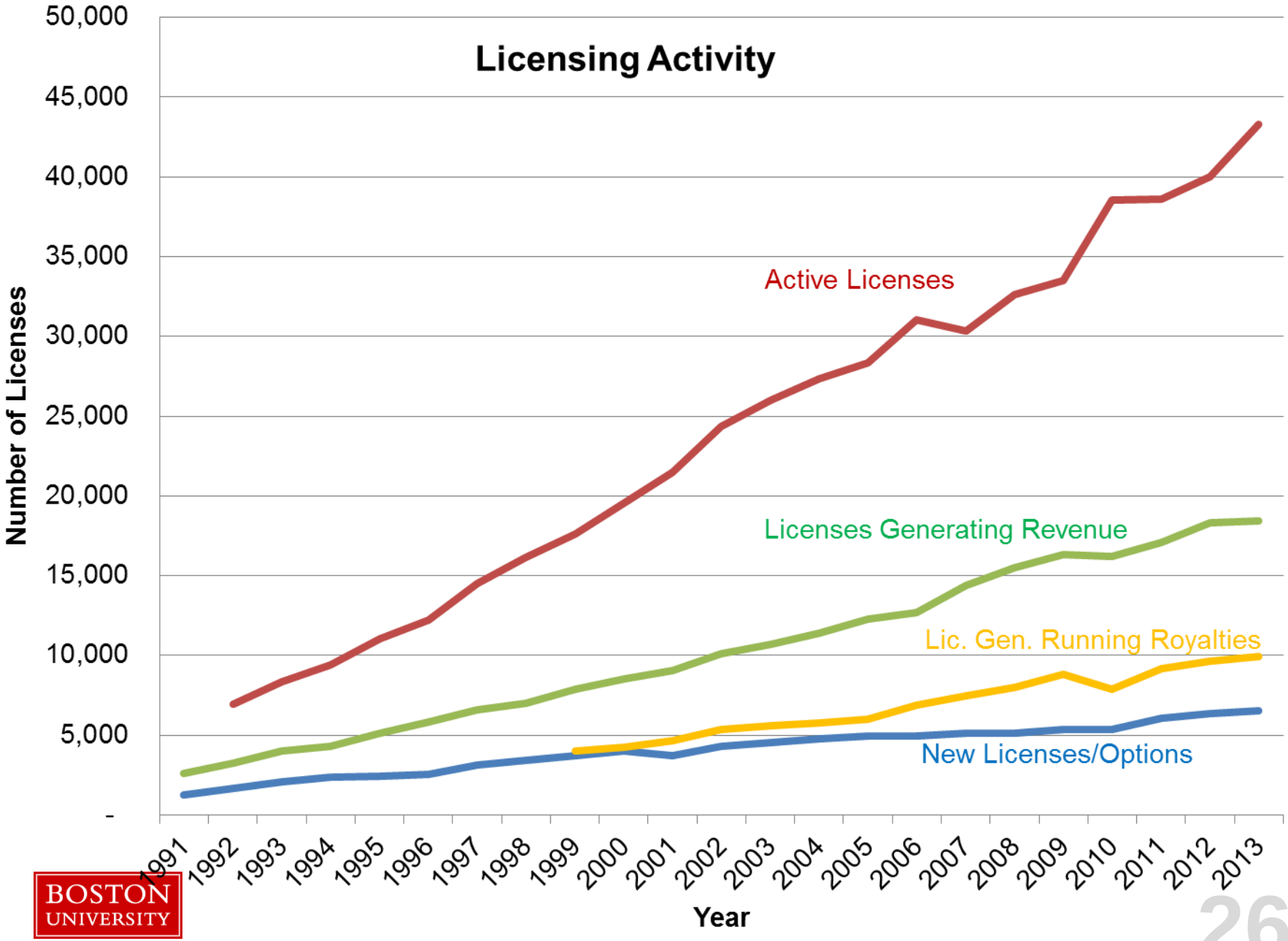

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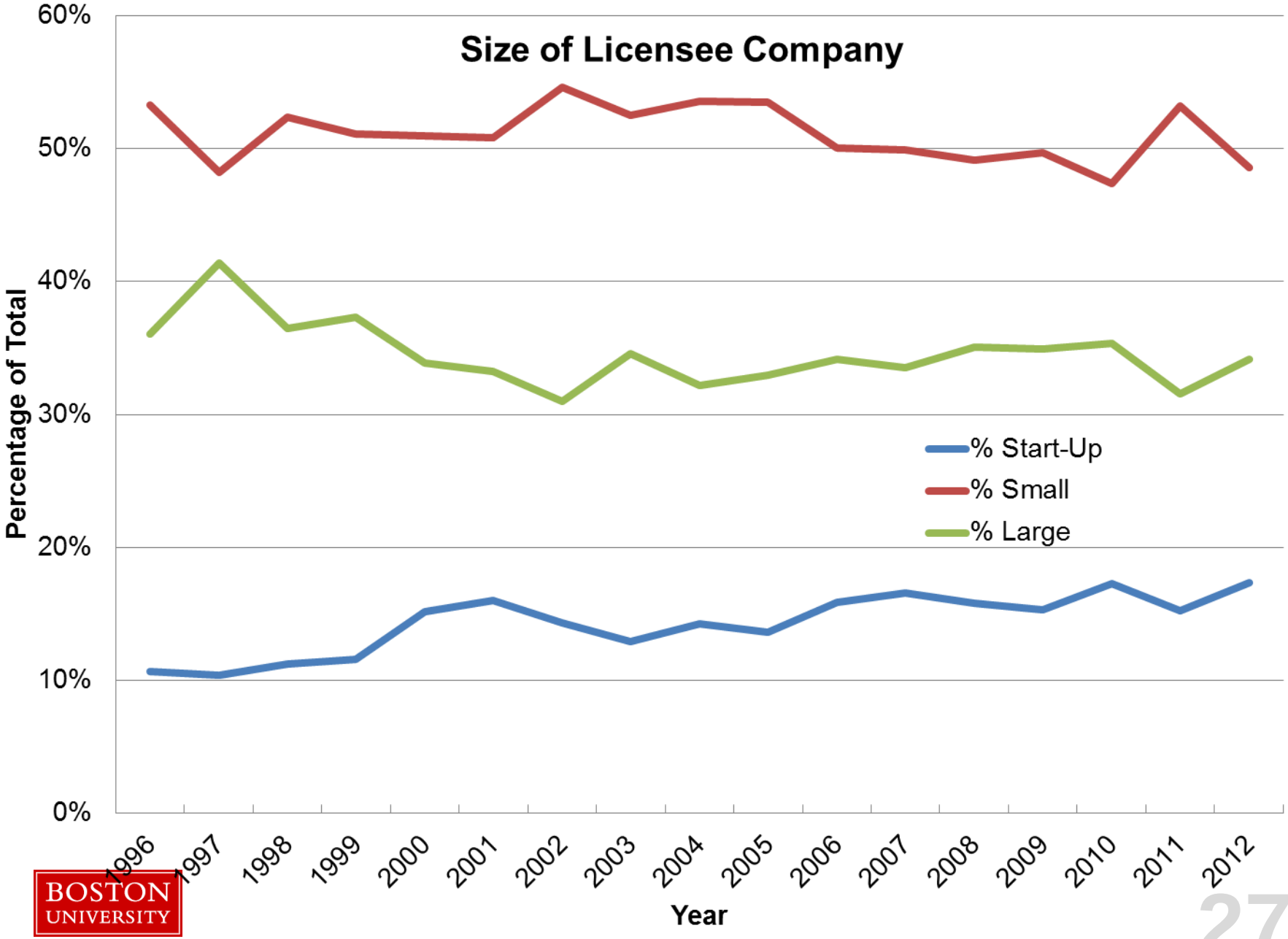

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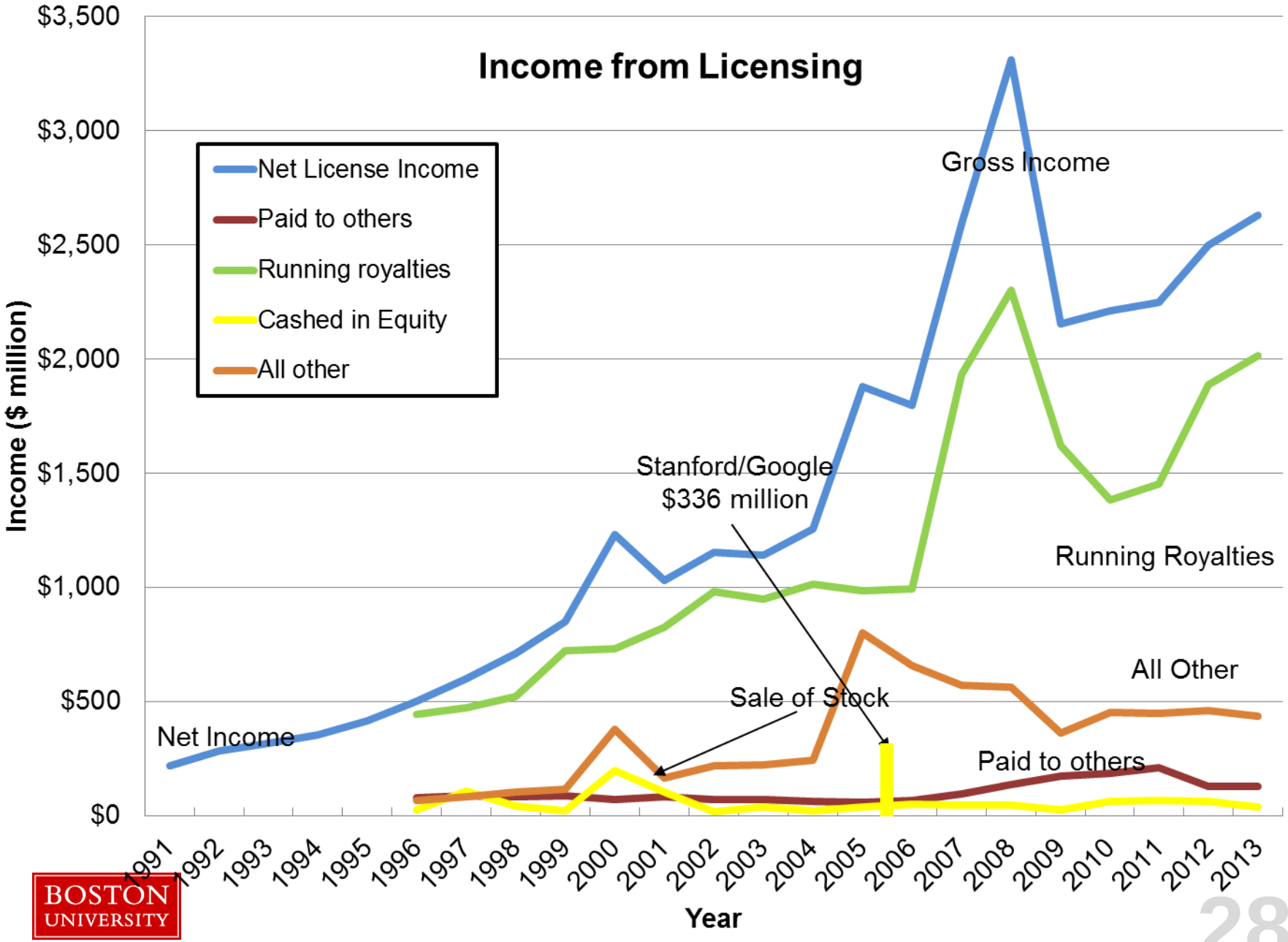

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Impact of Academic Research in Healthcare

- 153 marketed drugs and vaccines discovered in whole or in part in PSRI's
- 9% of all NDA's 1990 – 2007
- 21% of most innovative drugs
- $103 billion global sales

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SPECIAL ARTICLE

The Role of Public-Sector Research in the Discovery of Drugs and Vaccines

Ashley J. Stevens, D.Phil., Jonathan J. Jensen, M.B.A., Katrine Wyller, M.B.E., Sabarni Chatterjee, M.B.A., Ph.D., and Mark L. Rohrbaugh, Ph.D., J.D.

ABSTRACT

BACKGROUND

Historically, public-sector researchers have performed the upstream, basic research that elucidated the underlying mechanisms of disease and identified promising points of intervention, whereas corporate researchers have performed the downstream, applied research resulting in the discovery of drugs for the treatment of diseases and have carried out development activities to bring them to market. However, the boundaries between the roles of the public and private sectors have shifted substantially since the dawn of the biotechnology era, and the public sector now has a much more direct role in the applied-research phase of drug discovery.

METHODS

We identified new drugs and vaccines approved by the Food and Drug Administration (FDA) that were discovered by public-sector research institutions (PSRIs) and classified them according to their therapeutic category and potential therapeutic effect.

RESULTS

We found that during the past 30 years, 153 new FDA-approved drugs, vaccines, or new indications for existing drugs were discovered through research carried out in PSRIs. These drugs included 93 small-molecule drugs, 36 biologic agents, 15 vaccines, 8 in vivo diagnostic materials, and 1 over-the-counter drug. More than half of these drugs have been used in the treatment or prevention of cancer or infectious diseases. PSRI-discovered drugs are expected to have a disproportionately large therapeutic effect.

CONCLUSIONS

Public-sector research has had a more immediate effect on improving public health than was previously realized.

From the Institute for Technology Entrepreneurship and Commercialization (A.J.S.) and Office of Technology Development (A.J.S., J.J.J.), Boston University School of Management, Boston; the Norwegian Radium Hospital Research Foundation, Oslo (K.W.); and the Office of Technology Transfer, National Institutes of Health, Bethesda, MD (S.C., M.L.R.). Address reprint requests to Dr. Stevens at Boston University School of Management, 53 Bay State Rd., Boston, MA 02215, or at astevens@bu.edu.

N Engl J Med 2011;364:535-41.

What Drives Technology Transfer?

- Is it all about the money?

Dr. Mary Coleman, President, U. of Michigan

“I think many people are often confused about why we are interested in technology commercialization, in nurturing start up companies, and in facilitating more patents and license agreements.

Dr. Deborah Crawford, Senior Vice Provost for Research, Drexel University

I personally believe — so I'm not really speaking for Drexel University here — I personally believe that research universities have lost sight to some extent of their role in our nation. The fact that tech commercialization offices are created as cost centers in order, in some people's minds, to be self-sustaining is in fact the wrong model to use in the research university.

I oversee Drexel's research enterprise. I believe that tech commercialization is part of the overall cost of doing research for the nation. We receive federal funds to do research on the nation's behalf. And running a tech commercialization office is part of that responsibility set.

Right now, is that a commonly held belief? No it isn't. But there is a lot of conversation in the nation just now about the role of research universities. Because just like the biotech sector is kind of struggling to redefine itself at the moment because of the economic circumstances that are coming to bear on healthcare, so research universities are struggling with redefining their roles given the runaway costs of higher education, the fact that we don't have a full understanding of the complexity of our organization and ways to prioritize our internal investments in our universities to meet our missions.

I think part of the difficulties we all experience in tech commercialization is in part a consequence of this struggling to redefine our roles and be clear about our roles, and the respective roles of our partners in this.

Drivers of Technology Transfer

Driving Factor	Number of Institutions Ranking Factor First	%
Faculty service	51	39.2%
Translating research results	45	34.6%
Revenue maximization	15	11.5%
Other	15	11.5%
Research Support	4	3.1%
Risk Management	0	0.0%
Total	130	

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Source: Abrams, Leung & Stevens, 2010

Financial Performance

Financial Contribution	Number	%
Loss making	68	52.3%
Gross profitable	27	20.8%
Net profitable	14	10.8%
Self sustaining	21	16.2%
Total	130	

Source: Abrams, Leung & Stevens, 2010

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Universities and High Technology

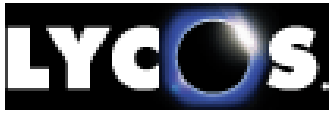
The Internet

CERN

University of Illinois Urbana-Champaign

University of Illinois Urbana-Champaign

(Stanford)



Carnegie-Mellon

MIT

Stanford

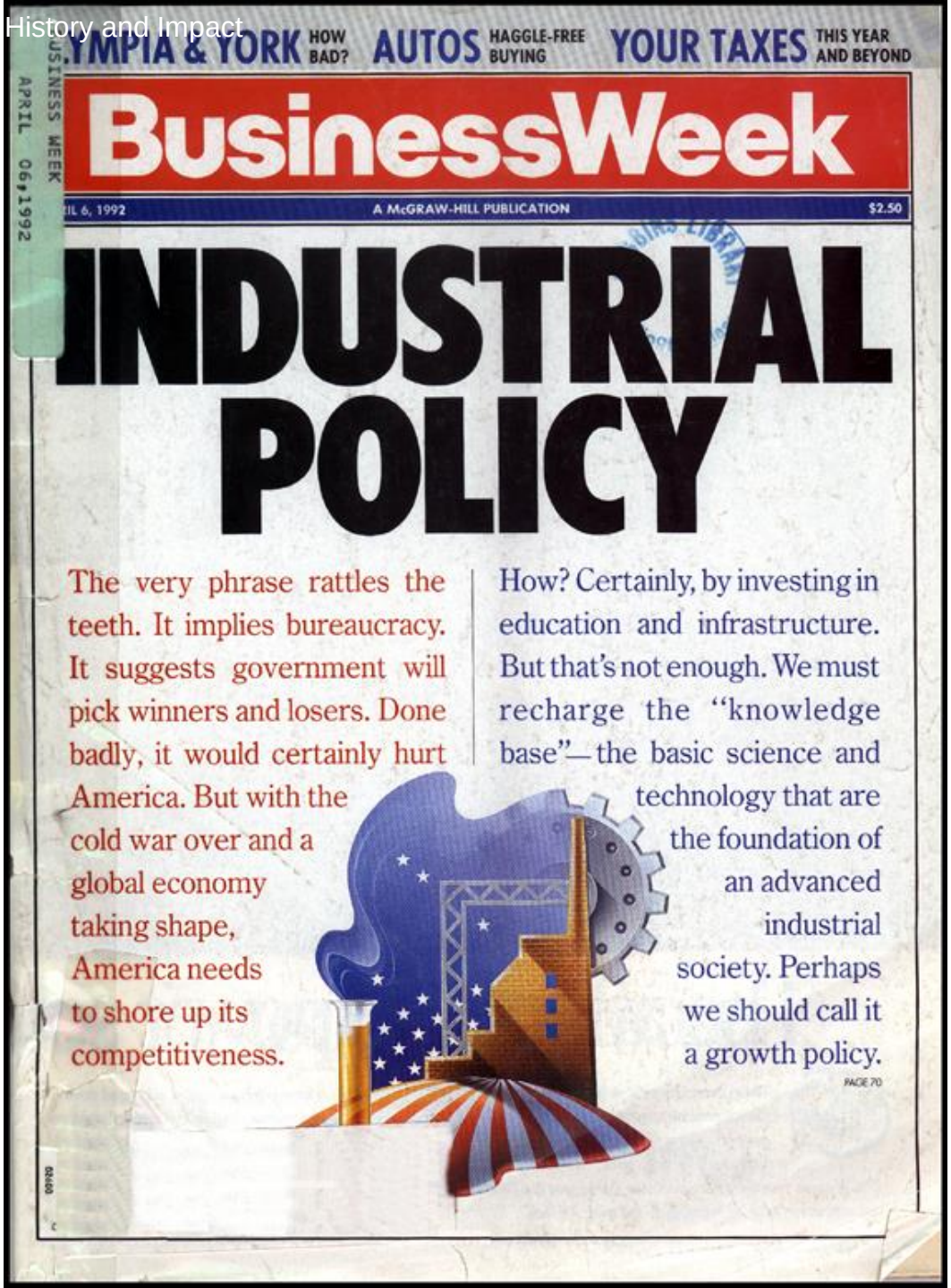
(Harvard)

Major Products in Many Sectors

- V-chip
- Hollow optical fibers
- PSA test
- Honeycrisp apple
- Cochlear implant
- Lightning detection technology
- Cell phone technologies

AUTM Better World Report

April 4, 1992

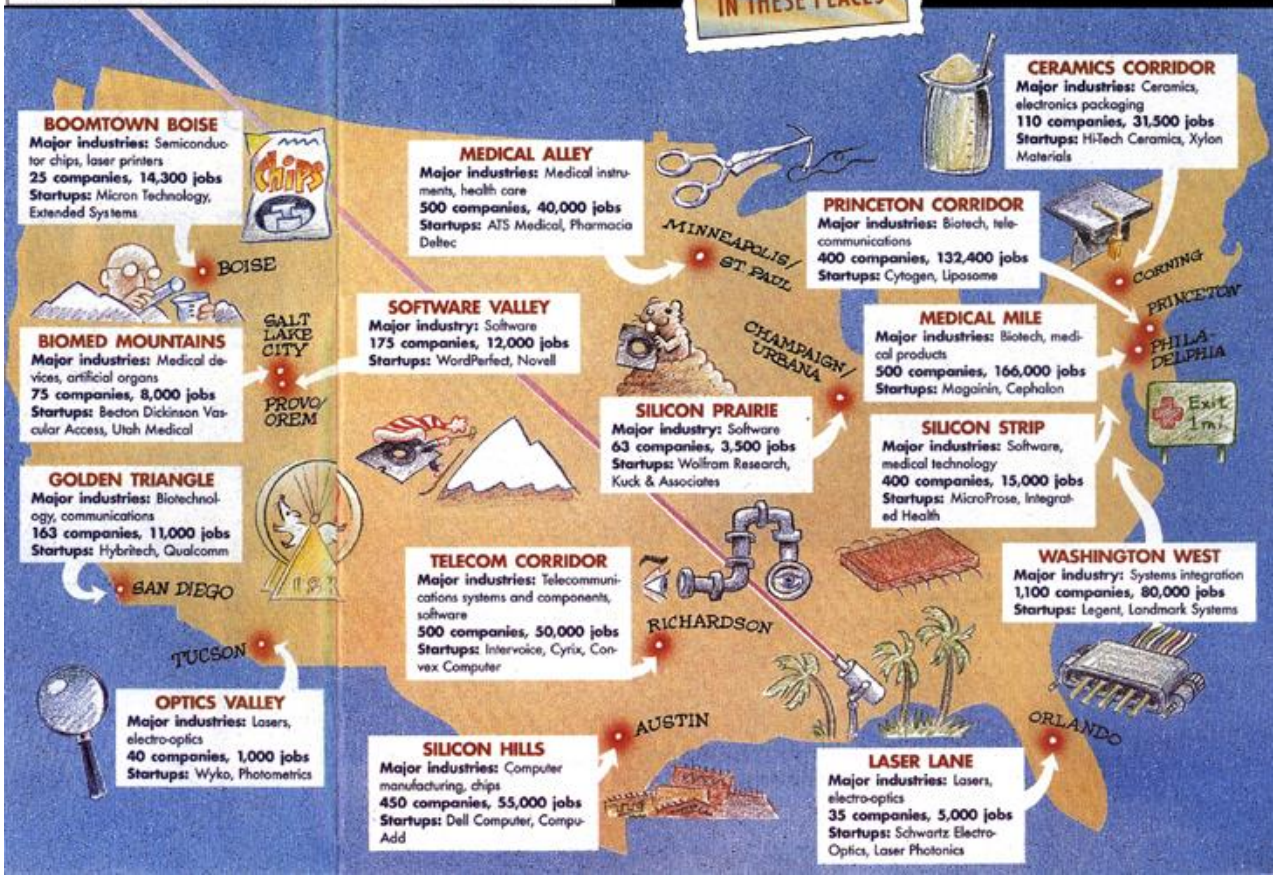

YMPIA & YORK HOW BAD?
AUTOS HAGGLE-FREE BUYING
YOUR TAXES THIS YEAR AND BEYOND
BusinessWeek
A McGRAW-HILL PUBLICATION
$2.50
INDUSTRIAL POLICY
The very phrase rattles the teeth. It implies bureaucracy. It suggests government will pick winners and losers. Done badly, it would certainly hurt America. But with the cold war over and a global economy taking shape, America needs to shore up its competitiveness.
How? Certainly, by investing in education and infrastructure. But that's not enough. We must recharge the "knowledge base"—the basic science and technology that are the foundation of an advanced industrial society. Perhaps we should call it a growth policy.
PAGE 70

October 19, 1992

HOT SPOTS

AMERICA'S NEW GROWTH REGIONS ARE BLOSSOMING DESPITE THE SLUMP

AT LEAST 600,000 PEOPLE HOLD HIGH-TECH JOBS IN THESE PLACES



Ingredients of a High Tech Cluster

- A major research university
- Quality of life
- Build on local industry
- Cooperation between local university, business and government
- Technology transfer from the university
- Funding sources -- state, VC, angels
- Incubators

Phases of Economic Development

- Start-ups
- New division of major US company
- Foreign companies move in
- Export lead growth

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Start-Up Companies

- 7,769 formed 1980-2010
  - 76% located in same state as institution
    - Every state except Alaska
      - 12.3% from California institutions
      - 11.8% from Massachusetts institutions
      - 363 by MIT
      - 349 by University of California System
      - 175 by University of Utah
  - 47% still active in 2010

AUTM Annual Licensing Activity Survey 1994-2010

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Licenses Granted

- 15% start-up companies
- 35% large companies
- 50% small companies

- 39% exclusive
- 61% non-exclusive

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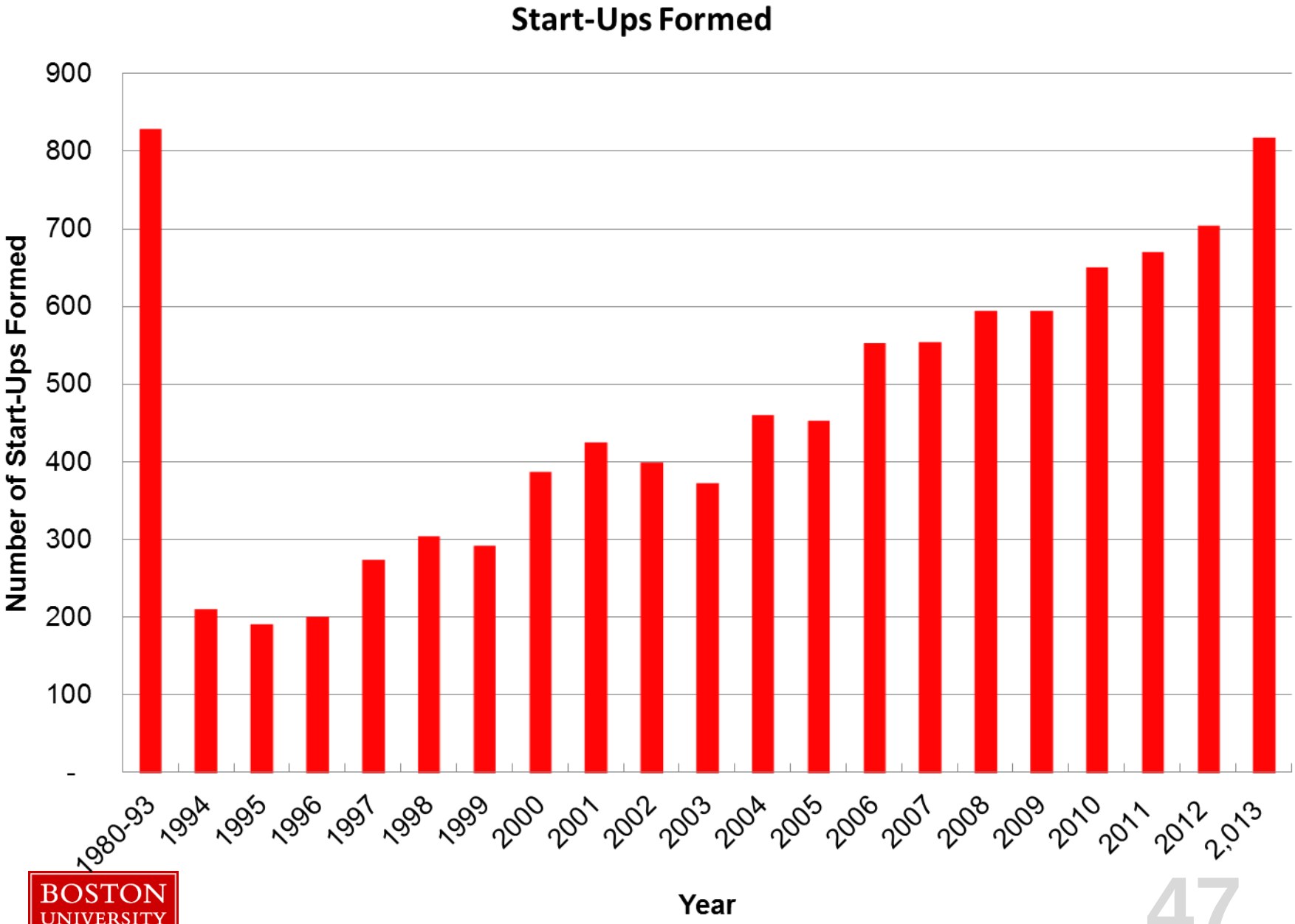

Start-Up Companies

- 9,966 formed 1980-2013
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    - Every state except Alaska
      - 12.3% from California institutions*
      - 11.8% from Massachusetts institutions*
      - 363 by MIT*
      - 349 by University of California System*
      - 175 by University of Utah*
  - 45% still active in 2013

AUTM Annual Licensing Activity Survey 1994-2012

* Through 2010

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Employment by Start-Up Companies

- Since 2011, question in AUTM Survey on employment by spin-outs
- Low compliance
  - ~35%
- Can extrapolate to full survey
- ~45,000 jobs
  - Stanford didn't respond
    - Google's 53,600 employees not included
  - Most universities reported small numbers
    - Probably only recent spin-outs
  - NC State reported ~7,000
    - Probably includes Cree

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The Transformation of Massachusetts

into

a Major Pharmaceutical Center

1970's and 80's – The Start-Ups

- In 1975, one pharmaceutical company in Massachusetts
  - US Headquarters of Astra AB of Sweden
- 1978 – Biotech companies started to spin out of Harvard, MIT, BU, Tufts
  - Biogen
  - Genetics Institute
  - Genzyme
  - Seragen

The Massachusetts Biotechnology Research Park

- First biotech-specific research park created worldwide
- Worcester, MA
  - F
  - A edical School
- Cam on
  - N

1980's – The First Big Pharma's

- BASF was first major corporation to move to Massachusetts (1989)
  - Massachusetts Biotechnology Research Park
  - Highly restrictive recDNA rules in Germany drove Big 3 abroad
- American Home [illegible] Genetics Institute (1992)

Universities

- Leaders in new biotechnologies
  - 8 Nobel Prizes 1960 – 1990
- Established offices of technology transfer early

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Funding

- Massachusetts was the birthplace of organized venture capital
  - 1947 – American Research and Development Corporation
- Substantial number of vc firms to fund the start-ups
- Proximity to Wall Street a plus


biogen idec
gsk
GlaxoSmithKline
Alkermes
Roche
ALGETA
Celgene
Takeda
AMGEN
ARIAD
Eisai
AstraZeneca
AsahiKASEI
SUNOVION
Healthy bodies, healthy lives
Ironwood
DSM
Bristol-Myers Squibb Company
MERCK
Research Laboratories
AMAG
PHARMACEUTICALS
MERCK
SERONO
CUBIST
PHARMACEUTICALS
Abbott
sanofi aventis
L'essentiel c'est la santé.
Shire
IPSEN
Innovation for patient care
pSivida
corp
Baxter
Johnson&Johnson
NOVARTIS
Aegerion
Pharmaceuticals
VERTEX
Pfizer

1995 – Rise of Biopharmaceutical Manufacturing

- Production of biopharmaceuticals inherently more closely tied to R&D than traditional pharmaceuticals
  - Produced from living cells
  - Sensitive to changes in production
  - Two step regulatory process
    - Safety and efficacy – BLA
    - Production – Premises License

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1995 – Rise of Biopharmaceutical Manufacturing

- Genzyme received substantial incentives to produce its first major product in Massachusetts

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1995 – Rise of Biopharmaceutical Manufacturing

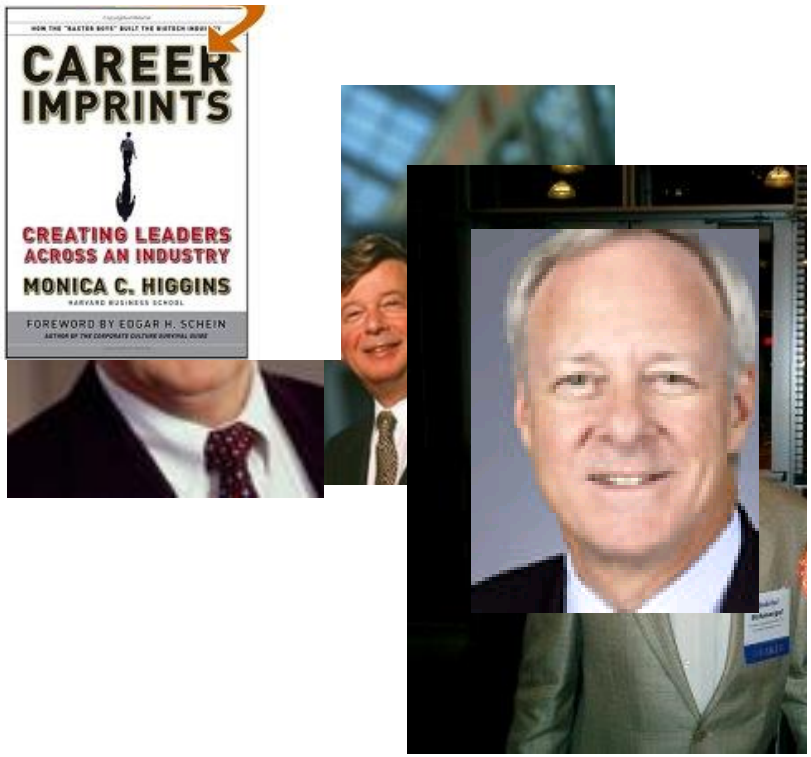
- Others followed

1995 – Rise of Biopharmaceutical Manufacturing

- 2003 HBS “Life Sciences” Summit
  - Professor Michael Porter
  - Convened the “Triple Helix” in one place
- Established biopharmaceutical manufacturing as a strategic goal
- Simplified permitting process
- Early success:
  - Avant Immunotherapeutics
- Recent success:
  - Bristol-Myers Squibb
  - Shire/TKT

Management

- Because no indigenous pharmaceutical industry, early management had to be imported
- The “Baxter Boys”
  - Jim Tobin at Biogen
  - Henri Termeer at Ger
  - Gabriel Schmergel at
  - Robert Carpenter at I



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2000 – Rise of FIBCO's

- Some of the early spin-outs successfully developed products
- Developed sales, marketing and corporate staffs

biogen idec

genzyme

THE MEDICINES COMPANY

Today

- World leading center of pharmaceutical R&D
- World leading center of biopharmaceutical manufacturing
- Diversified skill base in start-ups that have developed into FIBCO's

Lessons

- Took 25 years
- Built on exceptional strengths of Harvard, MIT, BU, Tufts, etc.
- Imported management
- Funding sources were in place
- A highly networked city

“Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole act of 1980.”

“Innovation's Golden Goose”
The Economist Technology Quarterly
Dec 12, 2002

FORTUNE

GOVERNMENT

The Law of Unintended Consequences

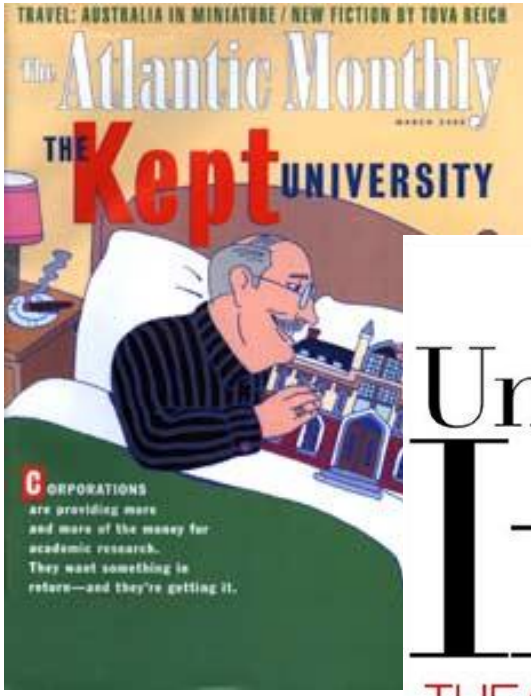
Twenty-five years ago a law known as Bayh-Dole spawned the biotech industry. It made lots of university scientists fabulously rich. It was also supposed to usher in a new era of innovation. So why are medical miracles in such short supply?

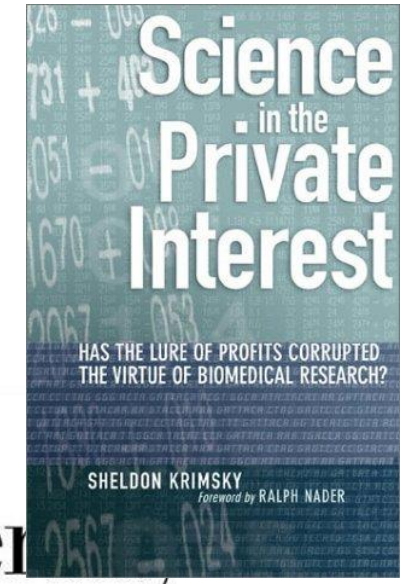
By Clifton Leaf

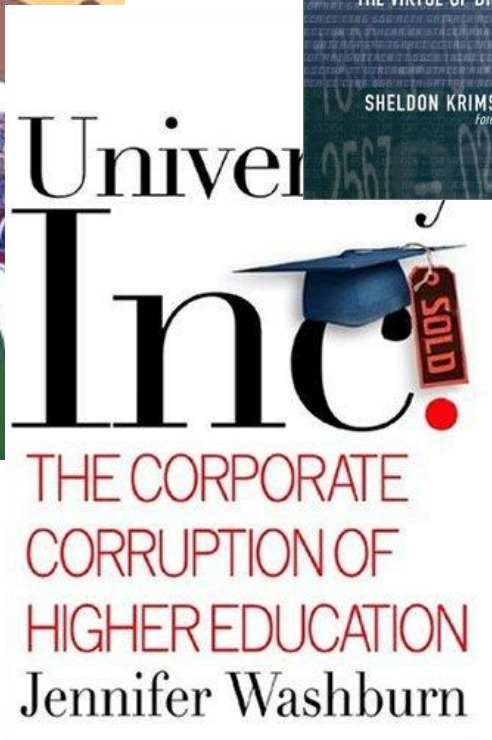
Even in the mute efficiency of international wire transfers, $540 million makes a noise when it lands in your bank account. To Kent Alexander, that sound was a thud—and in this case "not one single thud, but a lot of different thuds." All afternoon on July 21, 2005, Alexander, who is Emory University's general counsel, president Jim Wagner, and other senior members of the school's administration were receiving e-mailed reports from the finance de- partment: "121 million just hit!" And then, 50 minutes later, "183 million just hit!" Half an hour after that, an even richer stash arrived. *Thud.* "It was an out-of-body experience," says Alexander, 46. "By any definition, it's a huge deal. As one of our trustees was saying, 'It doesn't get any bigger than this on Wall Street.' "

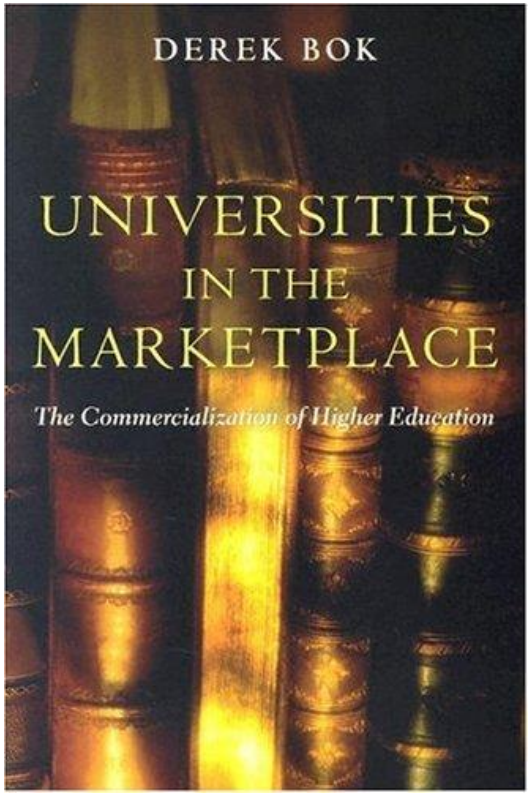
The deal in question had closed only days earlier, when a pair of biotech companies, Gilead Sciences of Foster City, Calif., and Royalty Pharma of New York City, outbid several other parties for Emory's roughly 20% stake in the powerful anti-retroviral drug Emtriva, which is used to treat HIV. The drug was developed more than 15 years ago by three of the university's scientists, working on federal research grants, but received FDA approval only in July 2003. Now, however, Emtriva (a modest seller in its own right) was being married to another antiviral in a single pill. The combination drug, called Truvada, was expected to have a worldwide market of nearly $1 billion in 2006. Emtriva was becoming a blockbuster. Citigroup set up the auction and hammered out the terms

There have been a lot of critics









The Criticisms

- Tech transfer offices are bad at commercialization
- Anti-Commons
  - Inhibiting scientific research
- Destroyed public confidence in the objectivity of universities
- Conflicts of interest of professors
- Global health
- Universities shouldn't profit from the results of research that was publicly funded.

Advantages

- Development of a body of expertise
- Funding for patent filings
- Protecting Academic Standards
- Ability to Implement Academically Appropriate and Socially Responsible Policies

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What are the alternatives to the University owning the IP?

Alternatives

- The Sponsor – usually the Government
- The Professor – the “Professor’s Privilege”
  - Was the most popular alternative
  - Common in Europe
- Starting in late 1990’s, Europe started adopting the US model
  - Only Sweden still on the Professor’s Privilege
- Starting in mid-2000’s, emerging countries following the US model

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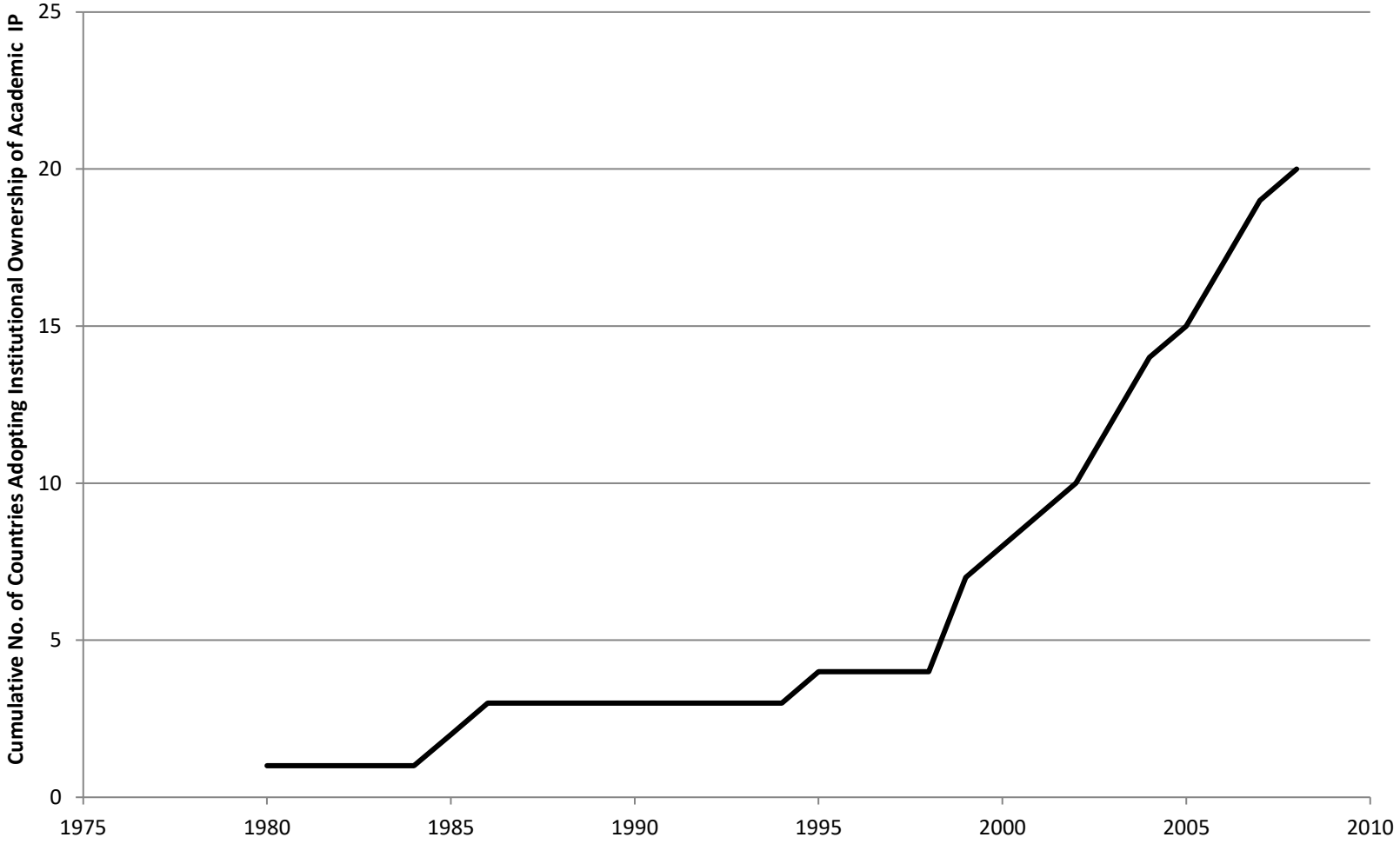
Cumulative Net Transitions to Institutional Ownership of Academic IP



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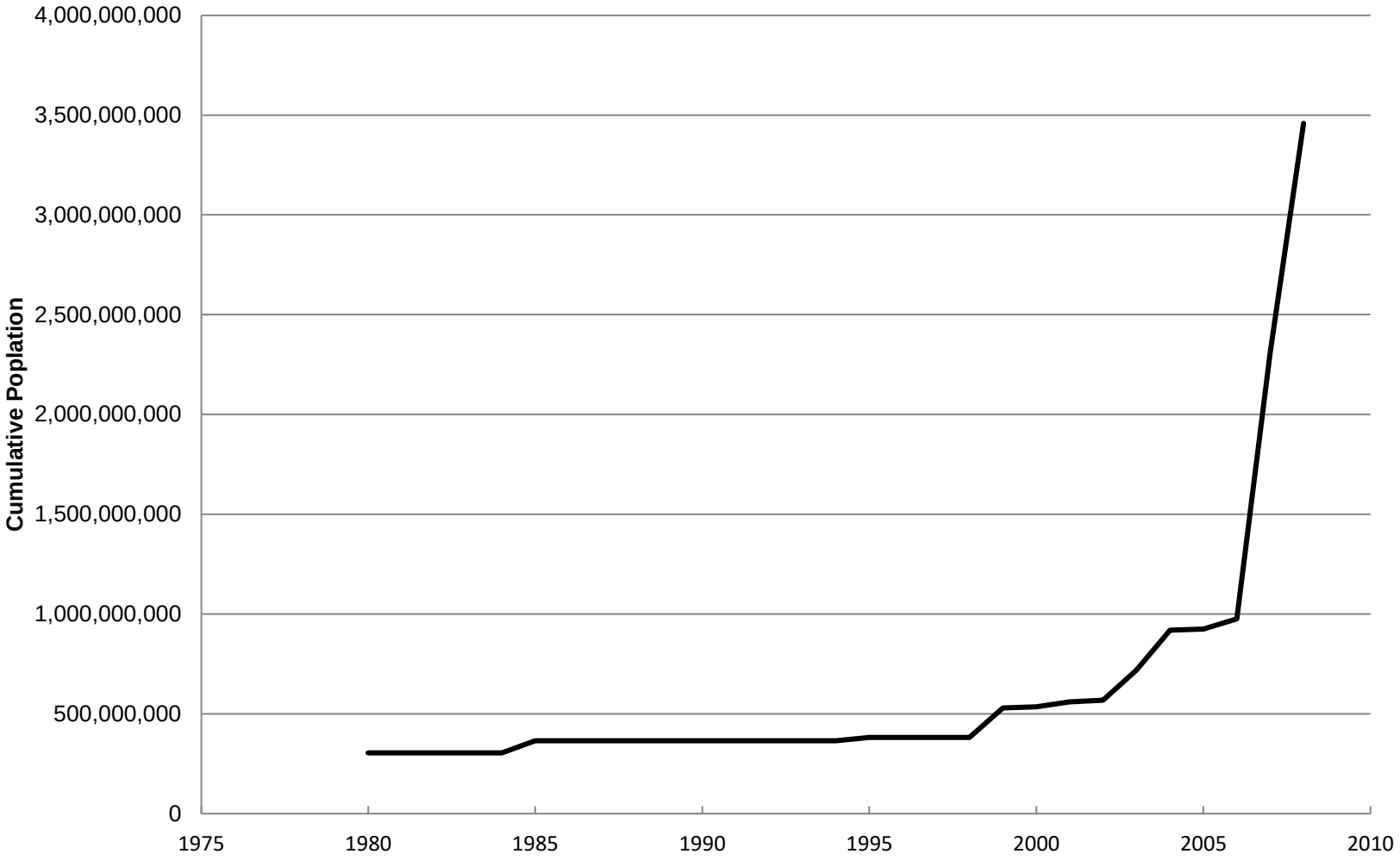
Cumulative Global Population Operating Under Institutional Ownership Model



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How does it work?

What Should Faculty Do If They've Made an Invention?

- Talk to the OTT early
  - Allows OTT time to evaluate the invention
  - Suggestions for research directions that improve the patent application
  - Provisional patent application WON'T delay publication
- Commit time and effort
  - Develop awareness of companies active in the field
  - Who's publishing?
  - Which companies are at the conferences they go to?
- What are the applications of the invention?
  - How will it be implemented in the market?
- Help OTT with marketing
  - Materials
  - Meet with companies

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Involvement in the Patent Process

- Preparation
  - Prior art
  - Experimental details
  - Uses – Claims
- Prosecution
  - Help the attorney overcome Examiner's objections
  - Interview with Examiner
- Promptly notify OTT and attorney of improvements

University Resources

- Office of Technology Transfer
  - "I'm from administration and I really am here to help you"
    - Evaluation
    - Marketing
    - Valuation
    - Negotiation
- Development funds
  - Pre-seed
  - Seed
- Company Development Capability
  - "Virtual incubator"
  - Physical incubators

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Be Patient

Remember:

"A hot academic invention is one that two companies are interested in."

Lita Nelsen
Director, OTL
MIT

What's Special About University Licenses?

University Spin-Out Companies

- Typically enabled by the University rather than organized by the University
- Driving force generally the faculty inventor, a post-doc or graduate student and an entrepreneur
  - Negotiate a license or option to the patents
  - Write business plan
  - Raise start-up funding
- License intended to ensure that
  - The technology is developed or the license terminated
  - The University is fairly compensated for success
    - Equity stake – spreads risk
    - Technology specific payments

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Intellectual Property

- Patents
  - Founding patents ("Flag pole") owned by Institution
  - Licensed to start-up
- Know-how
  - In heads of faculty and post-doc or graduate student
  - Faculty allowed one day per week for consulting
  - Critical for faculty to be on SAB and have consulting contract
  - Ideal arrangement is for the post-doc/graduate student to join the company
- Subsequent patents ("Picket fence") either co-owned by Institution and company or solely by company

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Unique Aspects of University Licenses

- No exclusivity for know-how ("technology")
- Certainly no license to trade secrets
  - Everything must be publishable – no trade secrets
- May not include license to improvements – certainly time limited
- Retained academic rights
- Federal rights
- Freedom to publish
- Strong Due Diligence requirements
- May not include on-going sponsorship of basic research
- Certainly will not include on-going clinical research relationship

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Unique Aspects of University Licenses

- US manufacture
- Very limited reps and warranties
- Stringent indemnification and insurance requirements
  - Harvard's endowment is $36 billion, MIT's $10 billion
- May have limitations on right to assign
- Limitations on use of University's name

What are the pitfalls?

Conflict of Interest

- A conflict of interest doesn't mean anyone's done anything wrong
- Probably means they're doing the right things

  "No conflict – no interest"

  David Blake, JHU, 1992
- Will impact their ability to participate in the clinical development of your work
- May impact the ability to receive corporate support of your work
- Some parts of the institution may resent the commercialization activities

Ownership

- Did the University have the right to own it?
  - Was it federally funded?
  - If original invention not federally funded, did it later become federally funded?

    "conceived of or first actually reduced to practice"
  - Did University elect title?
  - Are federal rights stated in the patent?
- Does University own entire right, title and interest?
  - Have all inventors assigned their interest to University?
  - Have all inventors signed the University's patent policy
  - Were any inventors omitted? E.g., Students? Do students fall under the patent policy?

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Ownership

- Does anyone else have any rights to it?
  - Are there material transfer agreements for materials used in the work that gave others rights to any inventions
  - Prior sponsors
  - Foundations with restrictive policies
    - Retain a financial interest -- University's problem
    - Limitations on licensing
  - Collaborators at other Universities
    - Look at publications that describe the work
    - Are there co-authors who are not co-inventors? Why not?
- All co-owners have an equal right to practice the patent without accounting to the others (in the US)
  - i.e., absent a pre-existing Inter-Institutional Agreement the exclusive license is no longer exclusive

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Inventorship, Inventorship, Inventorship

- The Achilles Heel of University patents
  - The first place infringers look to invalidate
  - Collaborators, publications, grants
  - Graduate students, post docs
  - Conception vs. reduction to practice
- Errors can be corrected
  - Patent Office rule changes facilitated corrections
  - If goodwill between the parties
  - If no conflicting pre-existing commitments

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