NITT SK 2014

Technology Transfer Policy in the USA and Its Implementation at Boston University

October 8, 2014

Bratislava, Slovak Republic

Dr. Ashley J. Stevens
President
Focus IP Group, LLC

Lecturer
School of Management
Boston University

The History of Technology Transfer in the US

The Fundamental Question

- Who owns the results of academic research?
  - They will control the commercialization of those results
- Only four options:
  - The professor who did the research and made the invention
  - The university that employed him/her
  - The organization that paid for the research
  - The company that wants to commercialize the invention

FOCUS IP GROUP, LLC

The US's Historic Approach

- "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

FOCUS IP GROUP, LLC

The US's Historic Approach

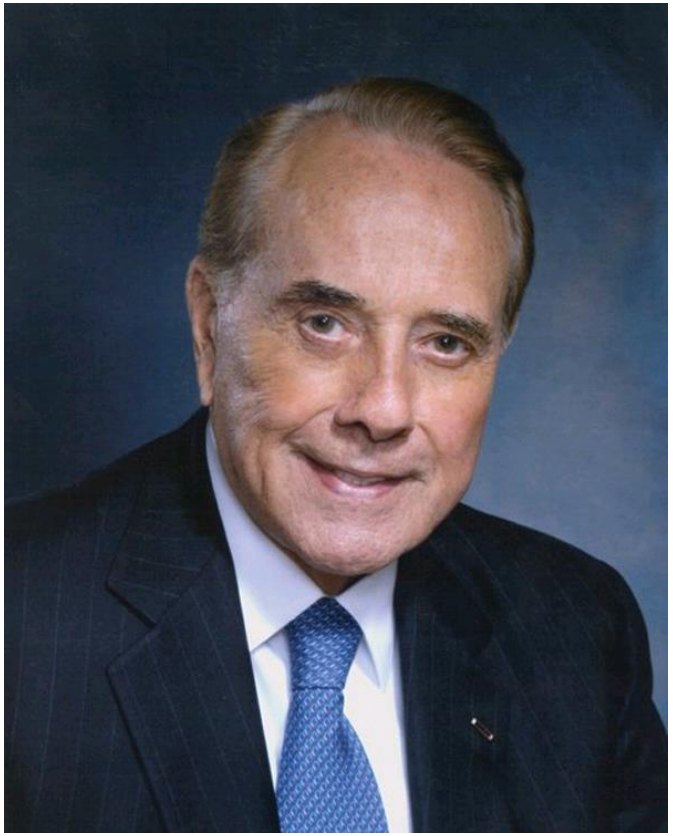
- By 1978, Government owned title to 28,000 patents and had licensed fewer than 4% of them
  - Included royalty-free licenses
  - Professor licensing his own inventions
- Inventions reported to the Government were declining, despite booming funding of NIH and NSF
- Research was regarded as "contaminated"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

FOCUS IP GROUP, LLC

What Was the Problem?

- Government wouldn't grant exclusive licenses
- Universities could request title
  - Bureaucratic
    - Every agency had its own policy
    - Decisions took 2-3 years
    - Contractor had to pay patent 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

FOCUS IP GROUP, LLC



FOCUS IP GROUP, LLC

The Bayh-Dole Act

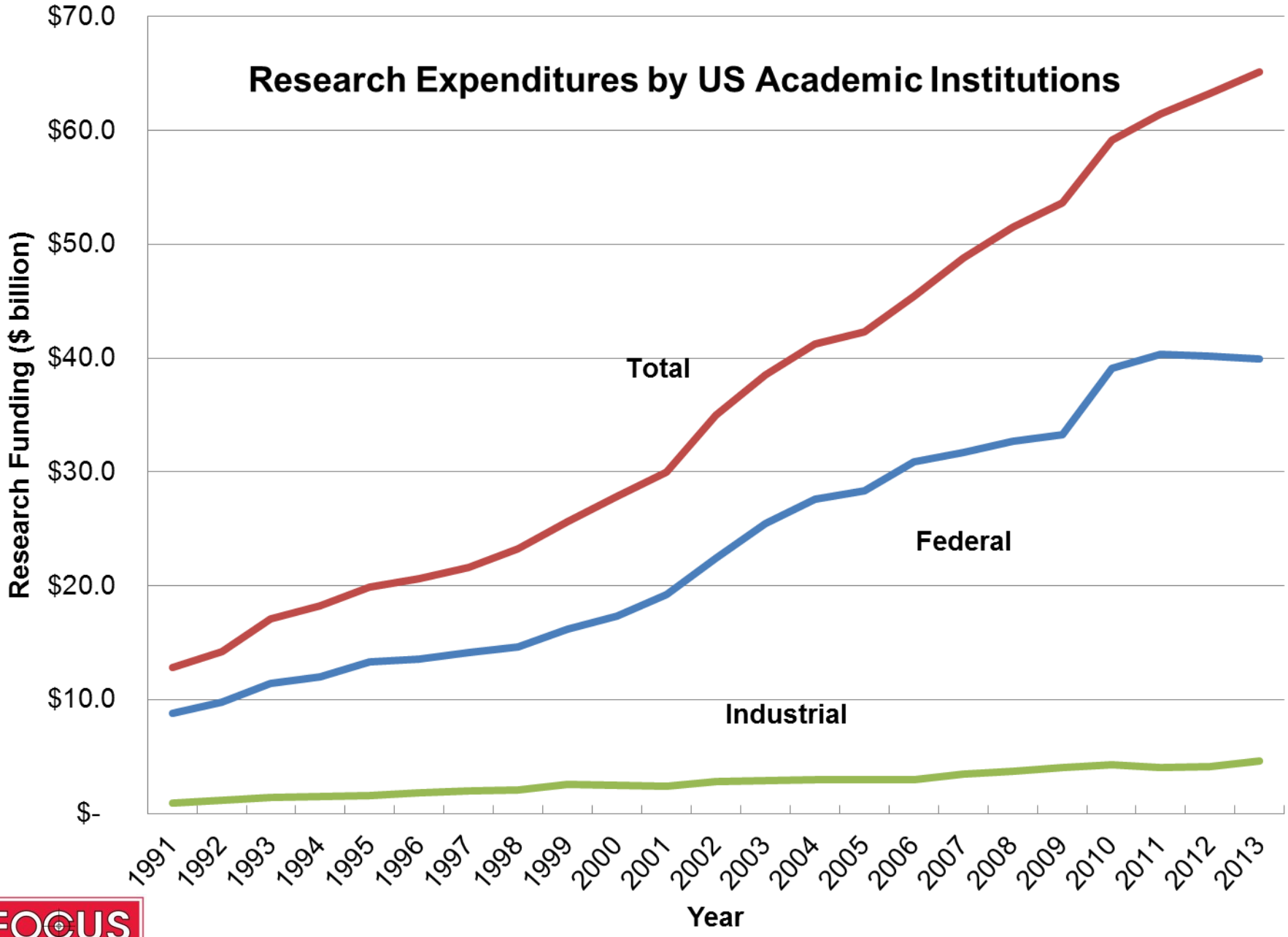
- PL 96-517 – The Patent and Trademark Amendments Act of 1980
- Main components:
  - Universities could elect to retain title to the results of Federally funded research
  - Universities were required to share proceeds with inventors
  - Most restrictions on licensing terms were removed
    - Can't assign (sell) the patent, only license it
  - 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
- Created the Institutional Ownership model of IP commercialization

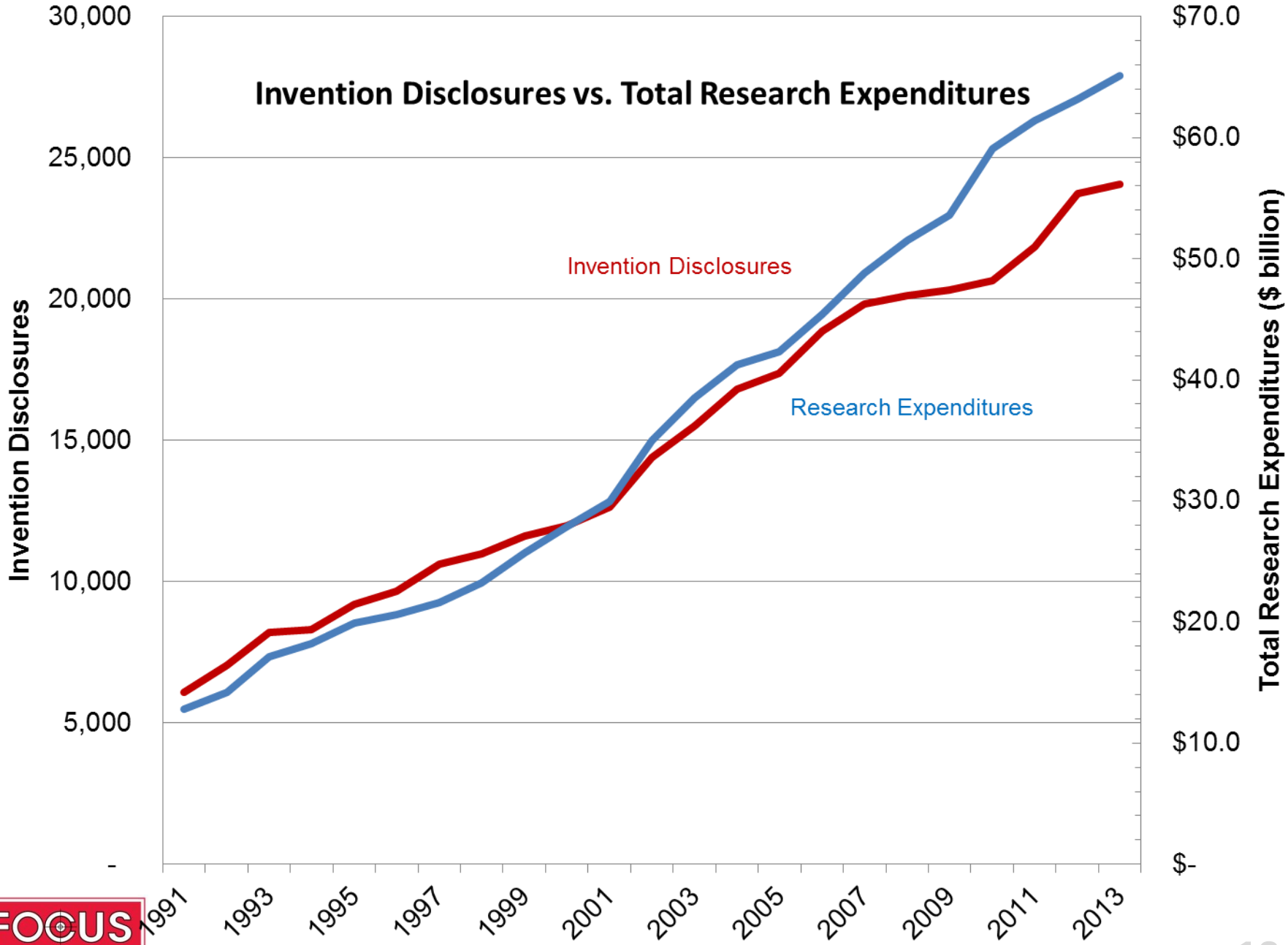
FOCUS IP GROUP, LLC

The Spread of the US Model

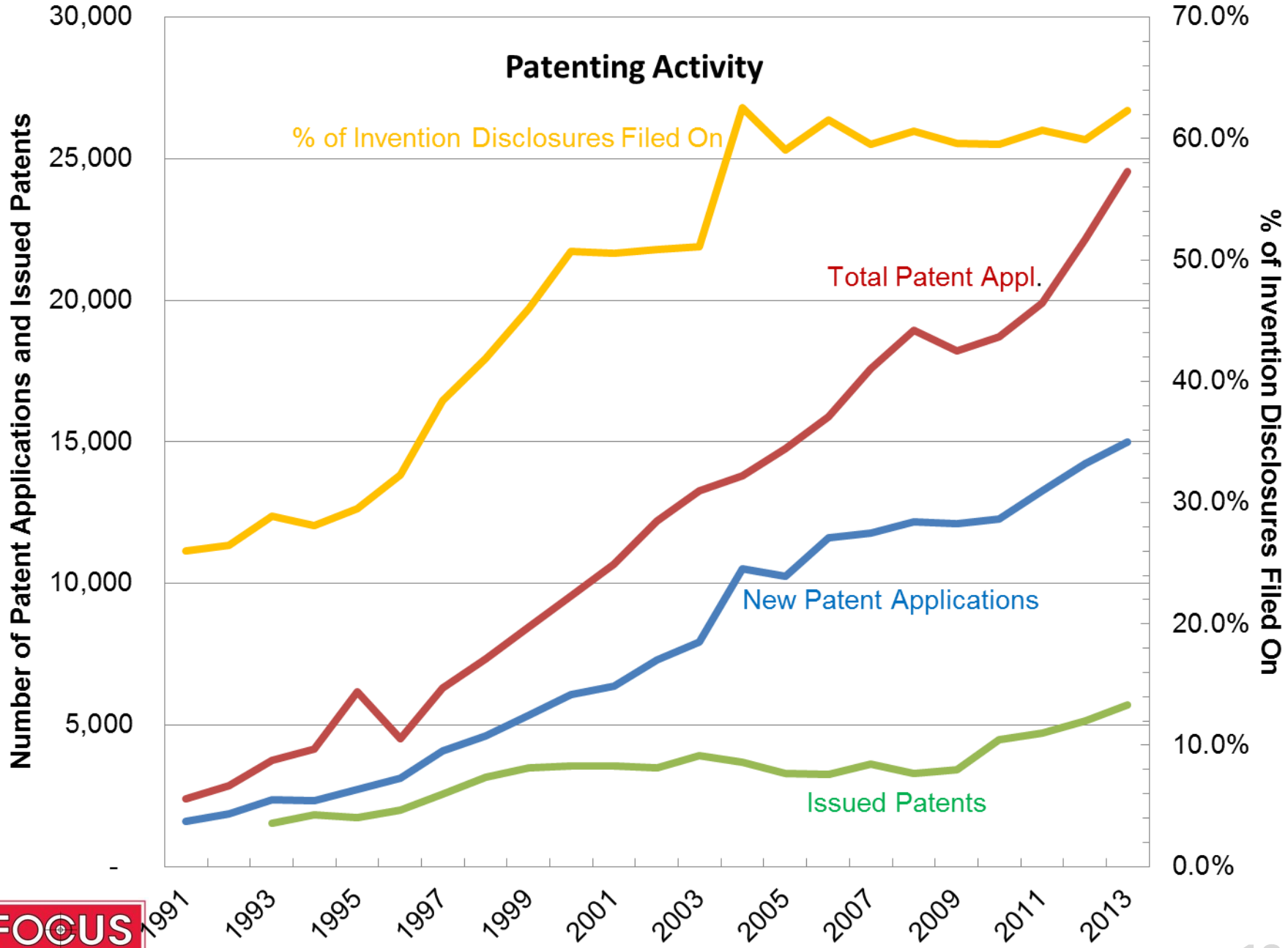
- Institutional ownership model of academic IP ownership has become dominant
  - Bayh-Dole in 1980
  - UK abolition of NRDC monopoly in 1988
- In Europe and Japan, “Professor’s Privilege” dominated historically
  - Transitioned to institutional ownership ~2000
    - Japanese National Universities became private corporations in 2004
- Institutional ownership model spreading in emerging economies
  - Brazil
  - S. Africa
  - India
  - Chile

The Scale of Technology Transfer in the US

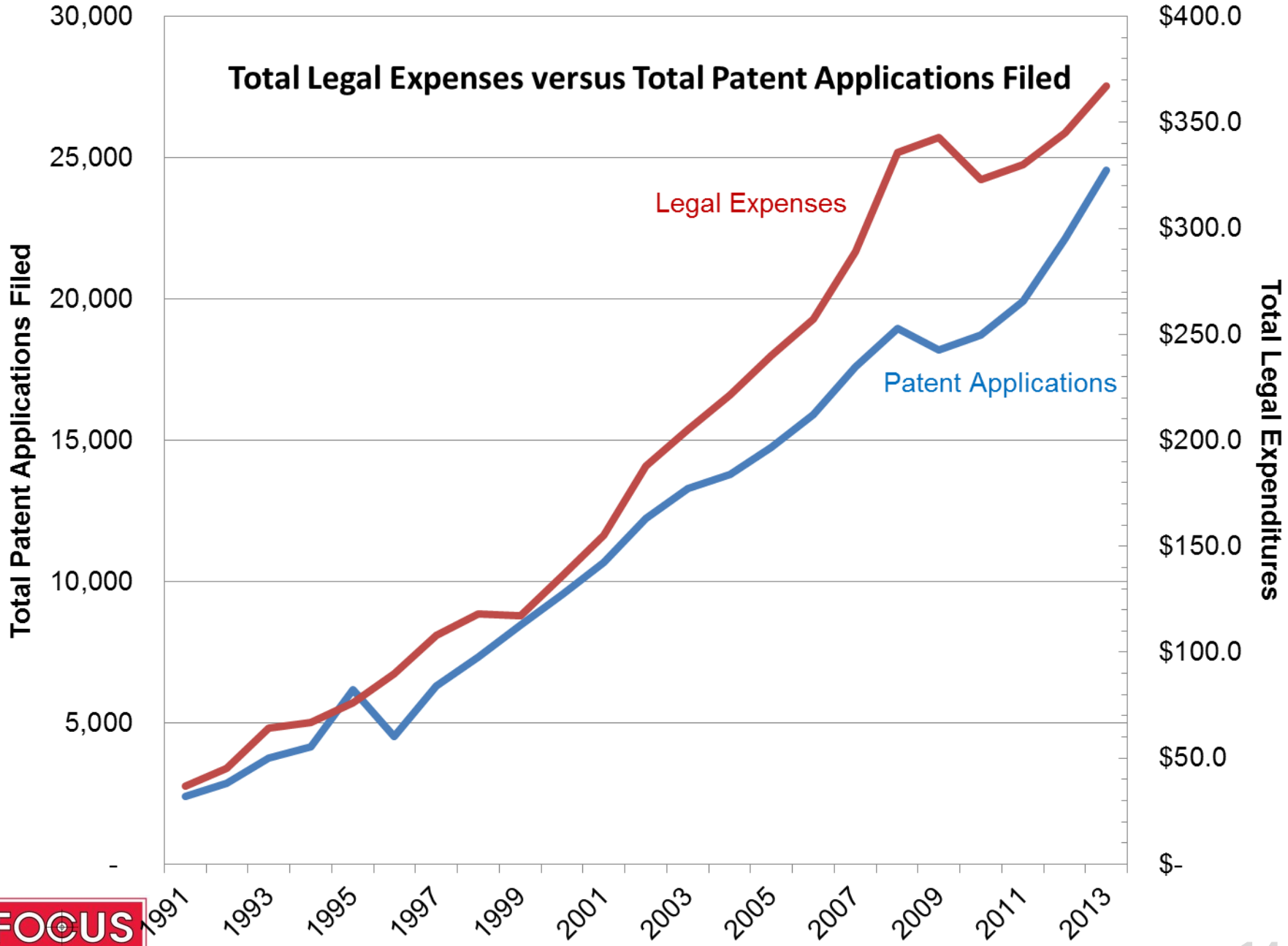




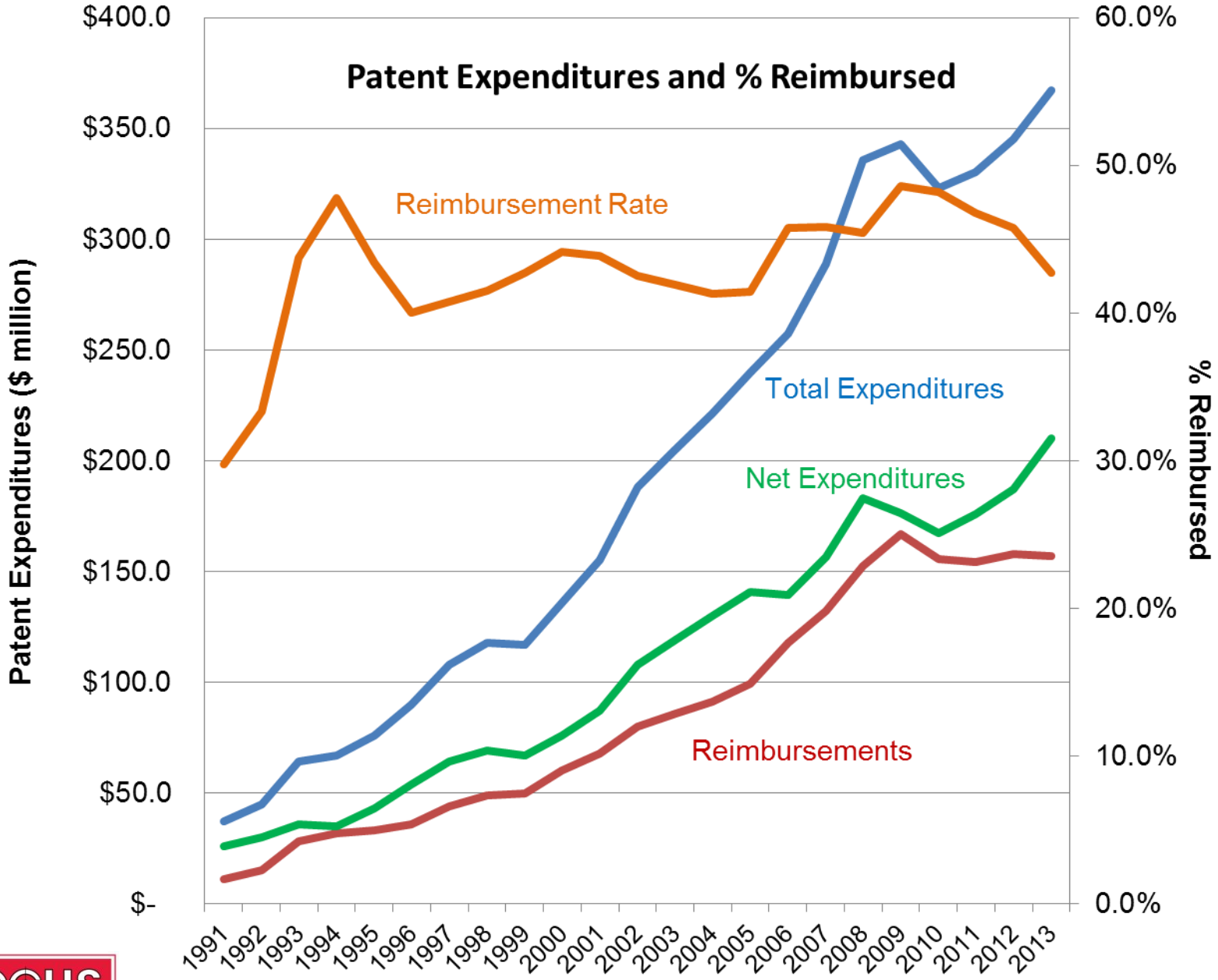
FOCUS IP GROUP, LLC



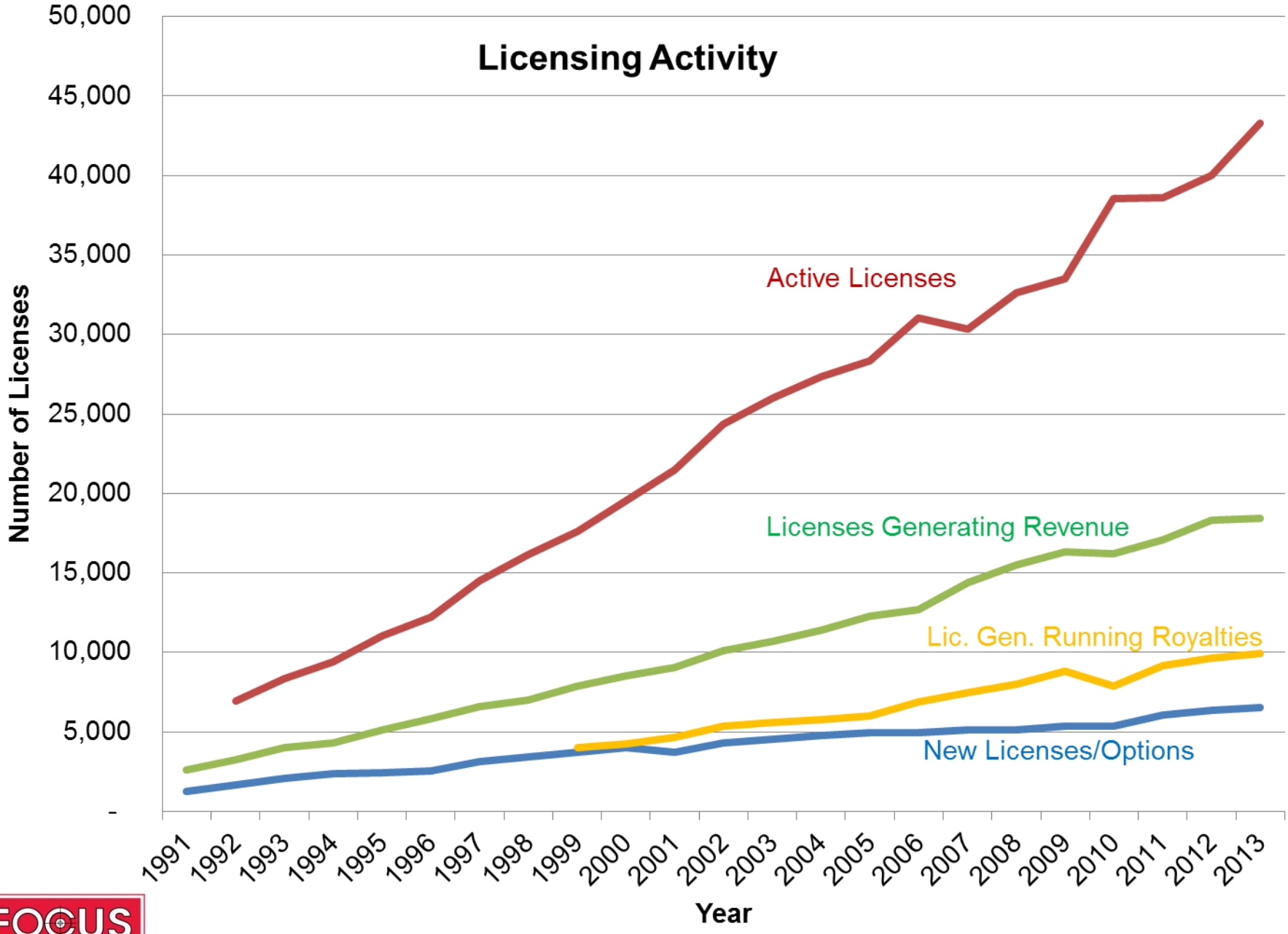
FOCUS IP GROUP, LLC



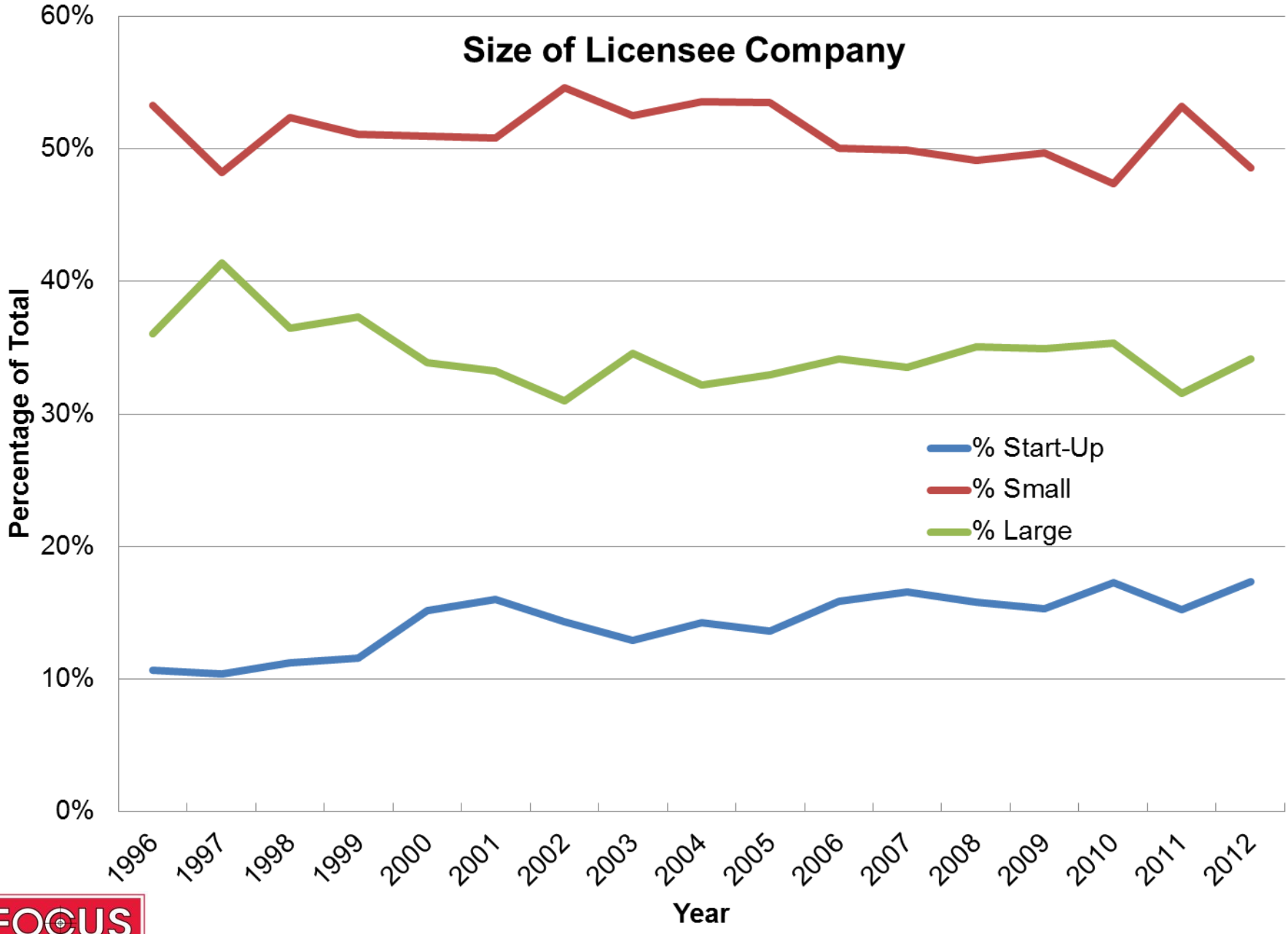
FOCUS IP GROUP, LLC



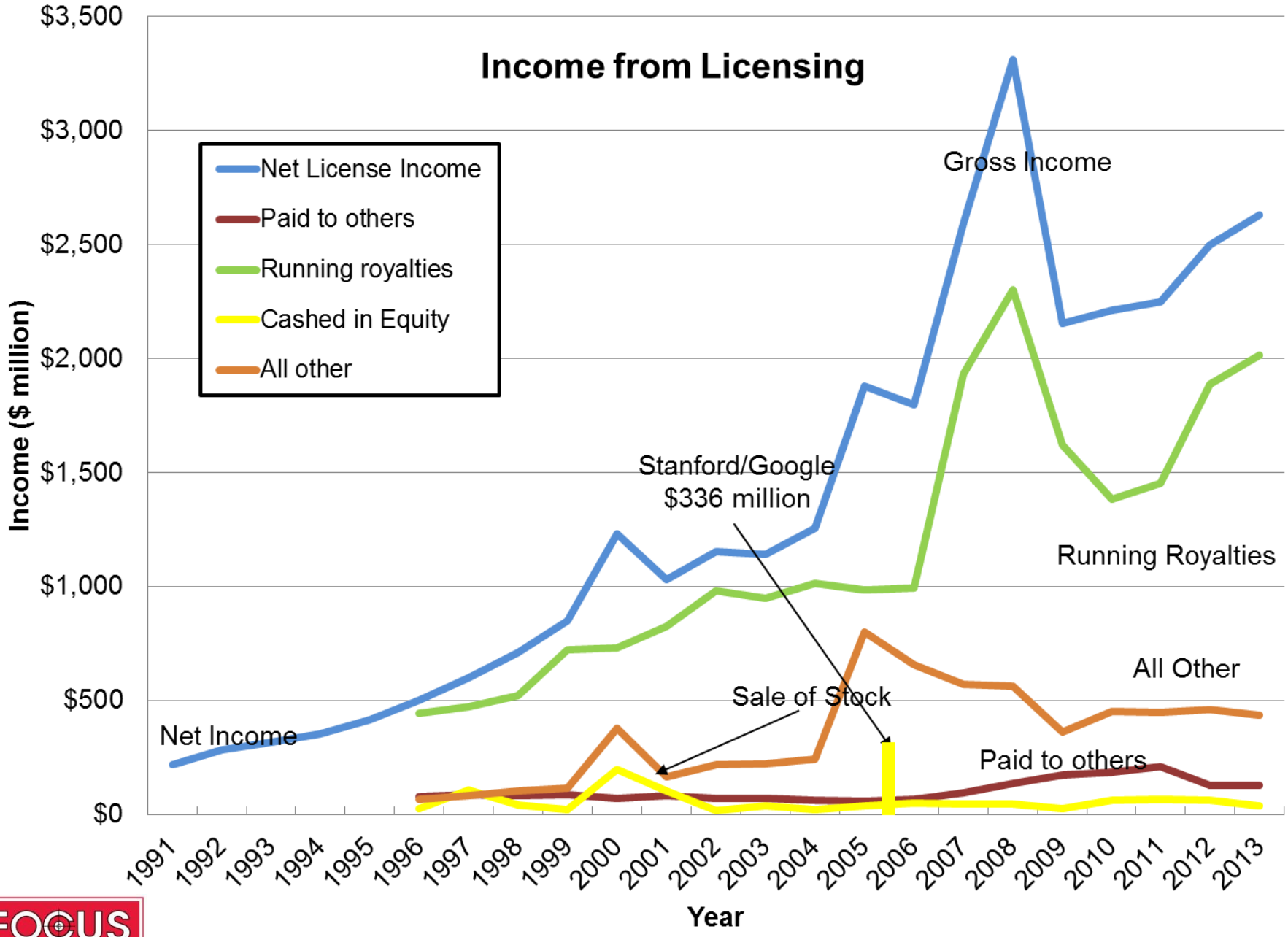
FOCUS IP GROUP, LLC



FOCUS IP GROUP, LLC



FOCUS IP GROUP, LLC



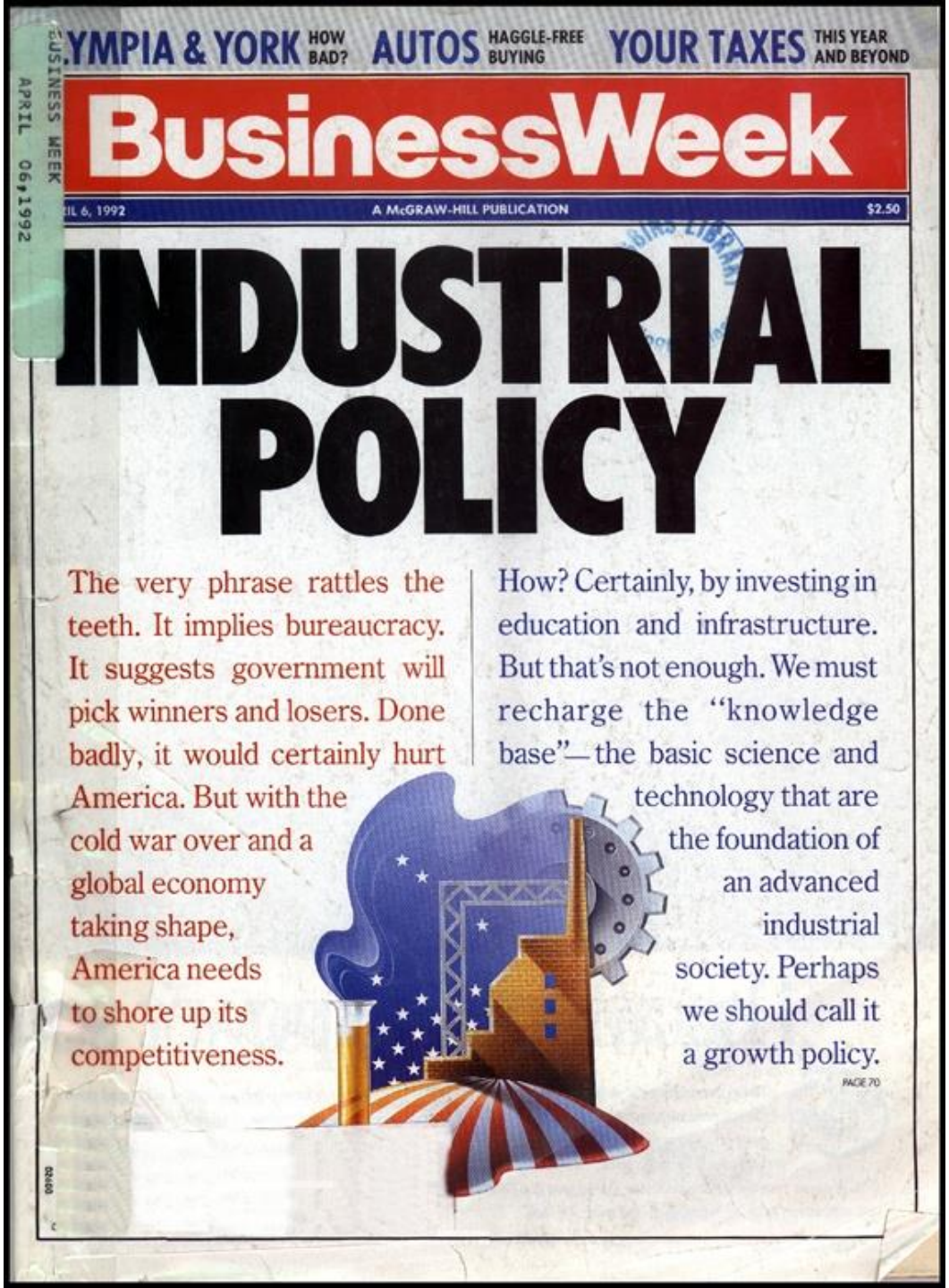
FOCUS IP GROUP, LLC

Academic Technologies Have the Power to Transform Economies

- Increasingly, companies do incremental research
- Fundamental breakthroughs come from the public sector
- Role of academic technology transfer to transform economies started to be realized soon after passage of Bayh-Dole

FOCUS IP GROUP, LLC

April 4, 1992

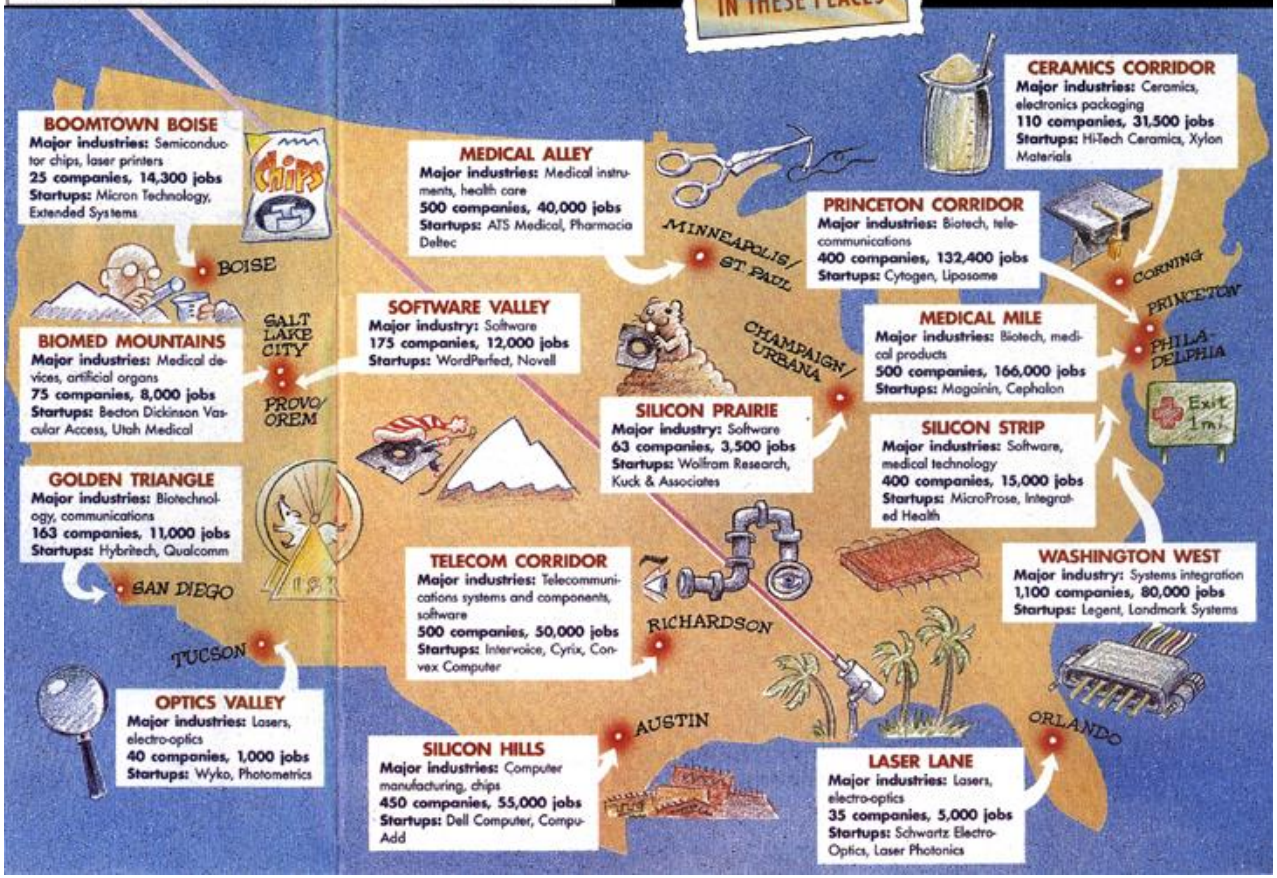

YMPIA & YORK HOW BAD?
AUTOS HAGGLE-FREE BUYING
YOUR TAXES THIS YEAR AND BEYOND
BusinessWeek
A McGRAW-HILL PUBLICATION
$2.50
INDUSTRIAL POLICY
The very phrase rattles the teeth. It implies bureaucracy. It suggests government will pick winners and losers. Done badly, it would certainly hurt America. But 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

<u>Phases of Economic Development</u>

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

FOCUS IP GROUP, LLC

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

<u>Phases of Economic Development</u>

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

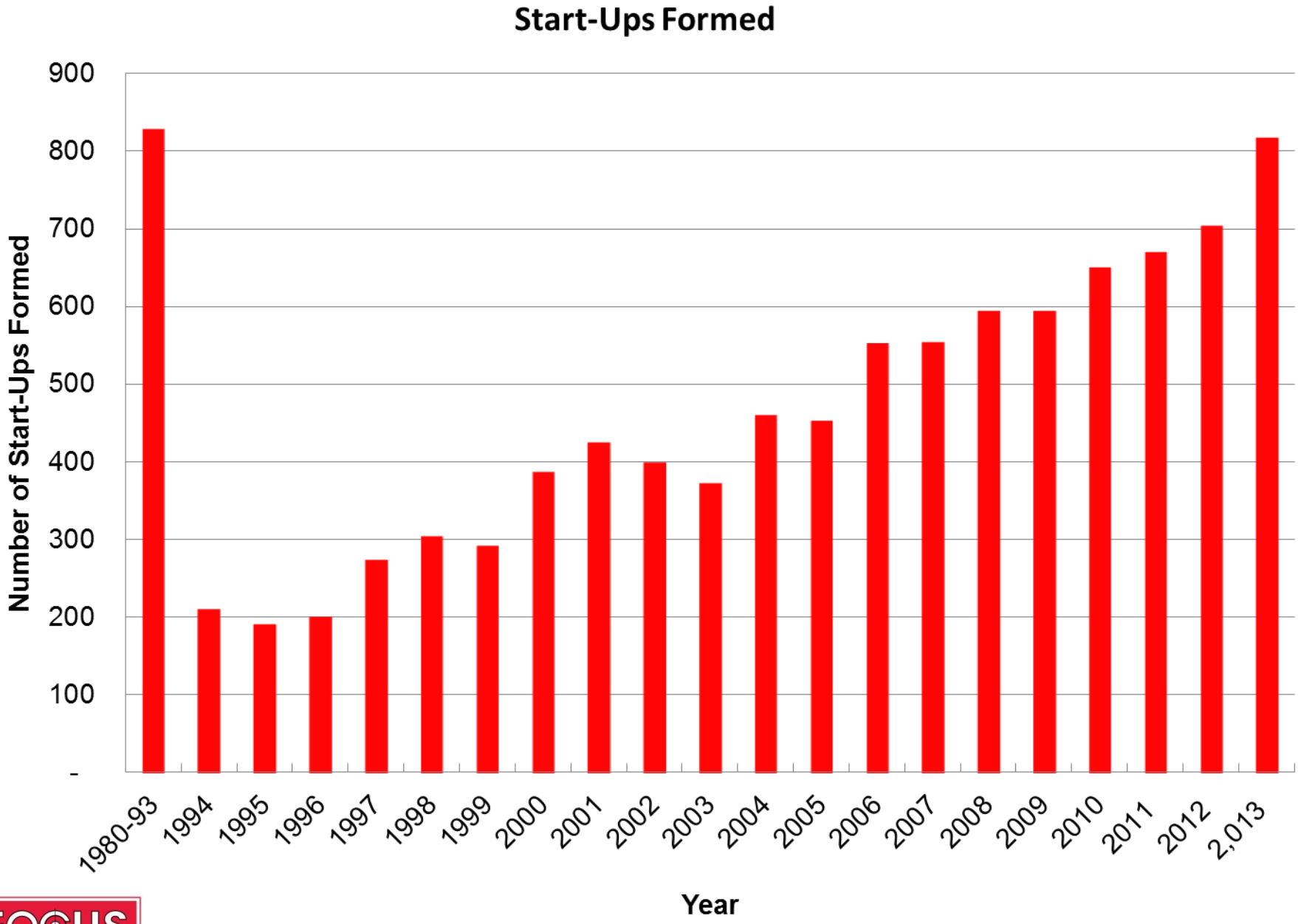
FOCUS IP GROUP, LLC

Ingredients of a High Tech Cluster

- Cooperation between local university, business and government.

The Triple Helix

- The new global paradigm for innovation-led economic development



FOCUS IP GROUP, LLC

Start-Up Companies

- 9,966 formed 1980-2013
  - 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*
  - 45% still active in 2013

AUTM Annual Licensing Activity Survey 1994-2012

* Through 2010

AUTM Survey Data on Economic Impact

- ~$100 billion of product sales
- ~55,000 jobs at spin-out companies
  - Excludes Google ($59.6 billion, 47,725 employees)

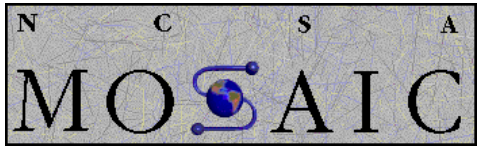
Two Areas of Particular Impact

- The Internet
- Healthcare

FOCUS IP GROUP, LLC

The Internet

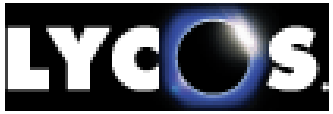
CERN



University of Illinois Urbana-Champaign

University of Illinois Urbana-Champaign

(Stanford)



Carnegie-Mellon

MIT

Stanford

(Harvard)

The Impact of Public Sector Research on Drug Discovery

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.

Impact of Public Sector Research on Drug Discovery

- 153 FDA approved drugs, biologics, vaccines and *in vivo* diagnostics
  - 13.3% of global sales
  - $103 billion worldwide sales in 2008
  - 9% of all NDA's approved by the FDA 1990-2008
  - 22% of most innovative NDA's approved

Stevens, A. J., et al. (2010). "The Contribution of Public Sector Research to the Discovery of New Drugs and Vaccines." Nature Biotechnology (submitted).

Number of Products

Type of Product	Number
New Chemical Entity	93
Biologic	36
Vaccine	15
Over the counter	1
In-vivo diagnostic	8
Total	153

Therapeutic Categories

Therapeutic Area	Number
Hematology/Oncology	40
Infectious Disease	36
Cardiology	12
Metabolic	12
CNS	12
Dermatology	7
Renal	7
Ophthalmology	6
Immunology	6
Gastroenterology	4
Women's Health	3
Allergy	2
Pulmonary	2
Urology	2
Anaesthesiology	1
Dental	1
	153

FOCUS IP GROUP, LLC

Discovering Institution	Number
National Institutes of Health	22
U. of California	11
Sloan Kettering	8
Emory University	7
Yale University	6
Children's Hospital, Boston	5
MIT	5
Salk Institute	5
Wisconsin Alumni Research Foundation	5
Columbia University	4
New York University	4
U. of Michigan	4
U. of Minnesota	4
U. of Texas	4
Brigham & Women's	3
Dana-Farber Cancer Institute	3
Harvard	3
Massachusetts General Hospital	3
Oklahoma Medical Research Foundation	3
Rockefeller University	3
Scripps	3
State University of New York	3
Tulane University	3
U. of Cincinnati	3

The Pharmaceutical Industry in Massachusetts

- In 1975, one pharmaceutical company in Massachusetts
  - US HQ of Astra AB
- Two events:
  - Spin-outs from Harvard, MIT, BU, Tufts, etc.
    - Some succeeded and are FIBCO's today
      - Biogen Idec, Vertex
    - Some stumbled and were acquired
      - Genetics Institute➔AHP ➔Wyeth-Ayerst ➔Pfizer
      - Genzyme ➔Sanofi
  - Massachusetts Biotechnology Research Park
    - Next to University of Massachusetts Medical Center
    - BASF first big pharma to move in
      - Discovered and developed Humira

FOCUS IP GROUP, LLC


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

Technology Transfer – a Unique Business Model

- Hire and pay staff
  - Must be comfortable operating in the fog of uncertainty of early stage technologies
- Train them to change the culture of professors/scientists
  - Start to identify useful inventions coming from their research
- Pay for patent applications on the inventions they eventually disclose
- Market the inventions
  - Inventions typically 4 years old when licensed
- Eventually license 25% of the inventions
  - Write off the investment in the rest
- Wait while the licensees develop the inventions into products to sell
  - Some technologies don't work or aren't cost effective
- Finally start to receive royalties on the successful inventions
- Give away 75-100% of the income
- Wait for the patents to expire

FOCUS IP GROUP, LLC

The Bottom Line – Red Ink

Financial Contribution	Number	%

Source: Abrams, Leung & Stevens, 2010

So, If It's Not About the Money, What Is It About?

- "It's The Economy, Stupid."

  Bill Clinton

- The major economic impact of technology transfer is not in the institution
  - If a university signs a license with a 5% royalty
    - or gets a 5% equity stake in a new company

    it's doing a good job
- But that means **95% of the economic impact is outside the university**
  - In the private sector
- This is the argument for government support

Boston University

FOCUS IP GROUP, LLC

Boston University at a Glance

- Founded 1839
- 33,000 Students
  - 130 countries
- 3,400 Faculty
- Charles River Campus and BU Medical Campus
  - 16 Schools and Colleges
  - 73 Centers, Institutes and Special Programs
- $450 Million in Grants and Contracts
- First University in America to:
  - Award an M.D. to a woman (1864)
  - Award a Ph.D. to a woman (1877)
  - Award a JD to a woman (1881)

FOCUS IP GROUP, LLC

Current Technology Transfer Activity (2013)

- $442 million research funding
- 43 invention disclosures
- 43 new patent applications
- 84 total patent applications
- 27 issued US patents
- $1.6 million income
- 10 licenses and options
- 4 start-ups
- 9 licensing staff
- 5 support staff

History of Technology Transfer at Boston University

- Pre-history
- Three phases:
  - Origins
  - Multiple programs
  - Consolidation
    - Modern era
- Willingness to experiment and innovate
  - And adapt and restructure

Origins

- Technology Development Fund
  - Founded 1975 as Community Technology Fund
  - Oldest University-Based Venture Capital Fund
- Office of Technology Transfer
  - Founded 1976
    - Pre-Bayh-Dole Act
  - Patenting, licensing, translational research

Diversification

- New programs added:
  - Health Policy Institute
  - Photonics Center
  - BioSquare
  - Fraunhofer Center

Consolidation

- Many of these programs found it difficult to attract funding
  - Outside of academic mainstream
  - Gradually evolved to more traditional academic models

Current Focus

- Faculty support
  - Mentorship programs
  - Translational research funding
  - Start-up assistance
    - Management team recruitment
    - Business plan development
    - Seed funding
  - Education
    - Student analysts
    - Teaching for-credit courses

FOCUS IP GROUP, LLC

Some Major Case Studies

Summit Technology, Inc.	Pioneer of LASIK surgery
Health Payment Review, Inc.	Pioneer of healthcare reimbursement software
Seragen, Inc.	ONTAK cancer treatment
GaN buffer layer	Blue LEDs
Symphogen A/S	Polyclonal antibodies
A123 Systems	Lithium batteries

FOCUS IP GROUP, LLC

Summit Technology, Inc.

- Resulted from a $25,000 translational research grant
  - 1984
  - Professor Richard Clarke, Chemistry
  - Apply excimer lasers to human tissue
    - Angioplasty
- Summit Technology formed 1985
  - BU invested
- First developed Photorefractive Keratotomy (PRK)
  - FDA approval for myopia in 1995
  - Astigmatism in 1998

FOCUS IP GROUP, LLC

Summit Technology, Inc.

- Developed laser-assisted in situ keratomileusis (LASIK)
  - Same lasers, different surgical approach
  - FDA approval in 1999
- Company acquired by Alcon
  - June 2001
  - $893 million
  - 600 employees

Health Payment Review, Inc.

- Idea came from Caterpillar Tractor
  - In US, health insurance is provided by employers
    - Caterpillar's medical director, Dr. Robert Hertenstein reviewed employee medical bills
      - Ensure conformity with billing policies
        - e.g., Unbundling
      - Doing it manually in spreadsheets!
      - Saving $500,000-600,000/year
    - Egdahl met him at a conference
      - Realized it had to be computerized to be scalable
  - Company incorporated in 1987
    - Initial contract with Caterpillar
      - Paid HPR $750,000
      - Received royalty on HPR's sales
      - Cheaper than for Caterpillar to do it themselves

FOCUS IP GROUP, LLC

Health Payment Review, Inc.

- Product called CodeReview
- "Pioneer" problem when trying to sell to insurance companies
  - Solved by offering a risk-free 3 month trial
    - Customer paid nothing upfront
      - 50% of savings
  - First customer saved $120,000 in first month
    - Terminated the deal
      - Wanted normal commercial deal
        - $100,000 license fee
        - $60,000 annual maintenance fee
- Company did IPO in 1995, valuing company at $150 million
- Acquired for $350 million in 1997
- Series of Harvard Business School Case Studies

- A technical success and a financial failure
- Initially founded in 1979
  - BU's answer to Genentech
  - Community Technology Fund invested
- Refocused and split into 4 companies in 1986
  - Main company focused on immunoconjugates
    - IL-2 and other proteins coupled with fragment of diphtheria toxin
      - ONTAK
      - Cutaneous T Cell Lymphoma
    - Partnered with Nycomed
  - Nycomed terminated
    - BU funded company
      - ~$100 million

- Adverse event in psoriasis trial decimated stock
  - Horrible dilution
  - Never recovered
- Became very political
  - John Silber was active in state politics
  - BU forced to sell company 6 months before drug approved
    - Ligand
    - $67 million
- Drug only approved in US
  - $50 million sales
  - Withdrawn from market because of manufacturing issues

- Copenhagen, Denmark
  - Leading privately held biotech in Denmark
  - Has raised $250 million to date
- Polyclonal antibody therapeutics
  - Dr. Jacky Sharon
- Initial contact at BIO2000 in Boston

- Products target cancer and infectious diseases
  - Lead candidate is Sym004
    - Anti-EGFR
      - Colorectal cancer
    - Phase 2
  - Partnership with Merck KgaA in 2012
- Additional partnership with Genentech
  - Sym009 vs undisclosed infectious disease target
- FDA required company to characterize every individual antibody
  - Products based on BU technology won't be commercialized
    - 30-50 Mab's
    - BU's return will come from equity stake
  - Current products typically have 2 MAb's

GaN Buffer Layer

- Invented by Dr. Ted Moustakas
  - Key enabling technology for blue LED's
    - Amorphous layer of GaN to bridge incompatible crystal structures
      - Synthetic sapphire
      - GaN
  - Licensed to Cree, Inc., Research Triangle
    - US leader in LED's
      - NC State spin-out
    - Uses a different process
      - Wanted to sell it's wafers to device makers
    - Litigation with Nichia Chemical Industries, Japan
      - Settled
    - Several other litigations
      - Settled

FOCUS IP GROUP, LLC

GaN Buffer Layer

- Cree didn't want to litigate further
  - BU negotiated first right to sue
  - Retained contingent law firm
  - Sued all major sellers of electronic devices with backlit screens
  - 25 settled through a deal through RPX in January 2014

FOCUS IP GROUP, LLC

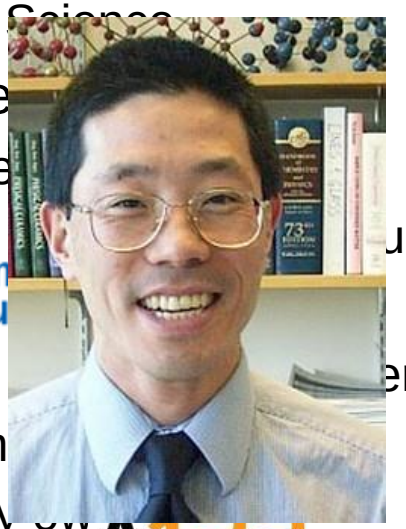
FOCUS IP GROUP, LLC

GaN Buffer Layer

- Cree didn't want to litigate further
  - BU negotiated first right to sue
  - Retained contingent law firm
  - Sued sellers of electronic devices with backlit screens
  - 25 sellers settled through a deal with RPX in January 2014
  - 15 still in litigation

A123 Systems

- Professor Yet-Ming Chiang
  - MIT, Materials Science
- Serial entrepreneur
  - American Superconductor
    - High temperature superconducting materials
    - Market
  - A123 Systems founded in December 2001
    - Self assembly of nanophosphate materials
    - Technology owned by MIT
      - Licensed to A123 Systems for 200,000 shares, $50,000 AMR plus royalties ($ paid as of IPO date)
      - Treasurers' Fund invested in later rounds



A123 Systems

- Company incubated in BU's Photonics Center Incubator
  - MIT do
  - Arrived
- Equity m
  - Press report estimated 500,000 share
  - d a venture fund
  - k
  - echnology from
  - core technology
  - Study

A123 Systems

- Stayed at BU till 2005
  - Moved to Watertown – 4 miles – then Waltham
- $249 million federal grant
- IPO in 2009
- High point -- 2010
  - 2,032 employees Manufacturing plants in China, Korea, Massachusetts and Michigan
  - Revenues $97 million
  - Net loss of $45 million
  - $500 million market cap
- Ultimately went bankrupt in 2012
  - Chinese competition
  - Assets bought by Wanxiang Group
    - $257 million
    - Now called B456

FOCUS IP GROUP, LLC

Thank you for listening.

Questions?

astevens@fipgllc.com

FOCUS IP GROUP, LLC