Benefits of IP-based Technology Transfer for the University, its Stakeholders, and Society at Large

Regional High-Level Summit for University Presidents and Senior Policy Makers on EIE

Osaka, Japan
November 25-27, 2019

Dr. Ashley J. Stevens
President

FOCUS IP GROUP, LLC

Organized by

WIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

In Co-operation with

OSIPP

INPIT

JPO

FOCUS IP GROUP, LLC

Agenda

- The history of academic research commercialization
- Its impact
  - Internet
  - Healthcare
  - Massachusetts

FOCUS IP GROUP, LLC

The History of Academic Research Commercialization

FOCUS IP GROUP, LLC

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
  - 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 1960's and 70's

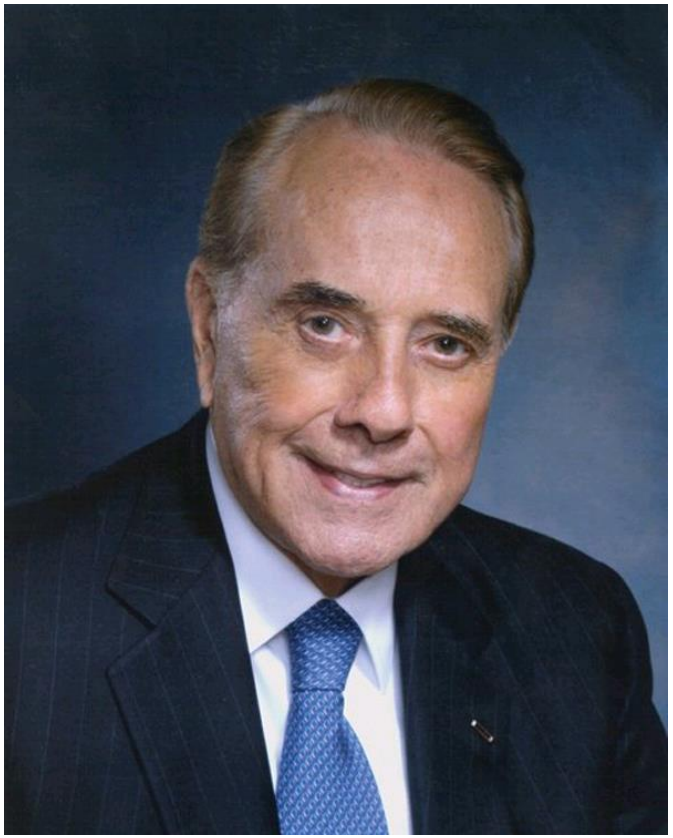
- By 1978, Government owned title to 28,000 patents and had licensed fewer than 4% of them
  - Included royalty-free licenses
  - Professor licensing his own inventions
- Inventions reported to the Government were declining, despite booming funding of NIH and NSF
- Research was regarded as "contaminated"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

FOCUS IP GROUP, LLC

What Was the Problem?

- Government wouldn't grant exclusive licenses
- 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

FOCUS IP GROUP, LLC

Key Success Factors of Bayh-Dole

- It established the “Institutional Ownership” model of technology management
- The government established very few impactful rules:
  - Share with inventors
  - Preference for small business
  - U.S. manufacturing
  - License not assign
- And then got out of the way
  - Virtually no changes in the 40 years since
    - Allowed a solid body of best practices to emerge

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
  - IN Europe, only Italy and Sweden still use Professor’s Priviledge
- Institutional ownership model spreading in emerging economies
  - Brazil
  - S. Africa
  - India
  - Chile

FOCUS IP GROUP, LLC

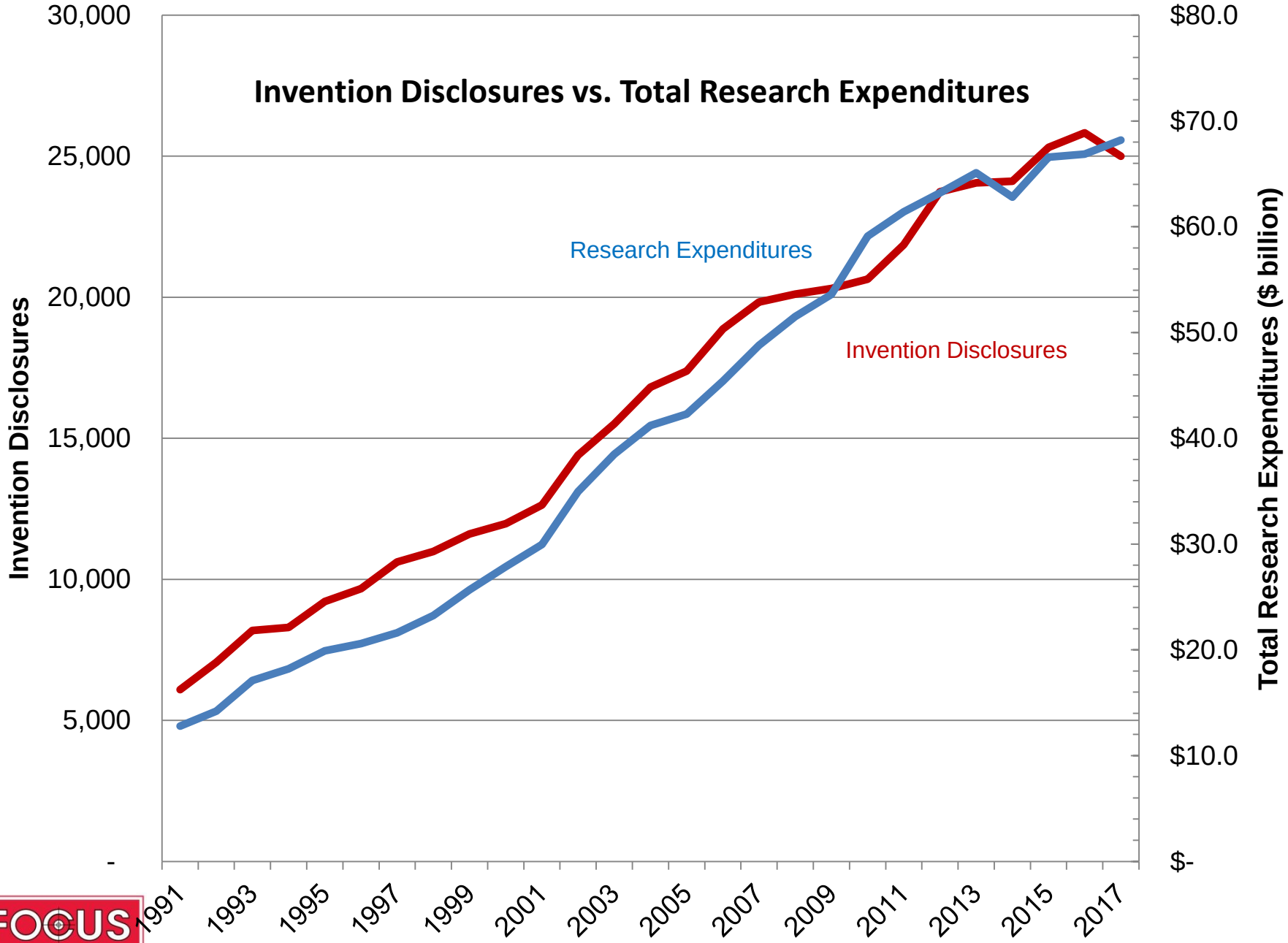
The Impact of Research Commercialization

FOCUS IP GROUP, LLC

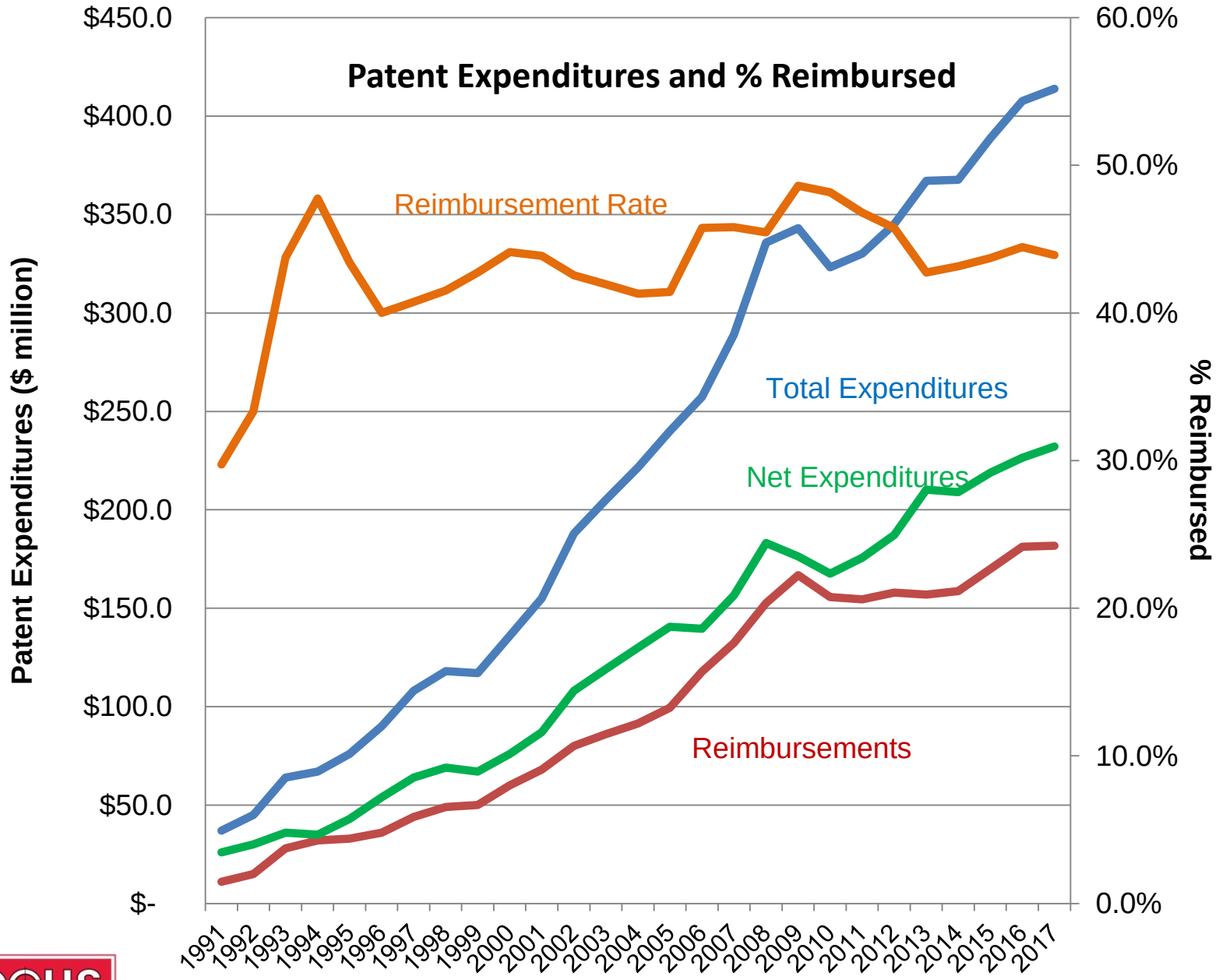
Development of Technology Transfer Ecosystem in U.S.

- All data from the AUTM Annual Licensing Activity Survey
  - 1991-2007

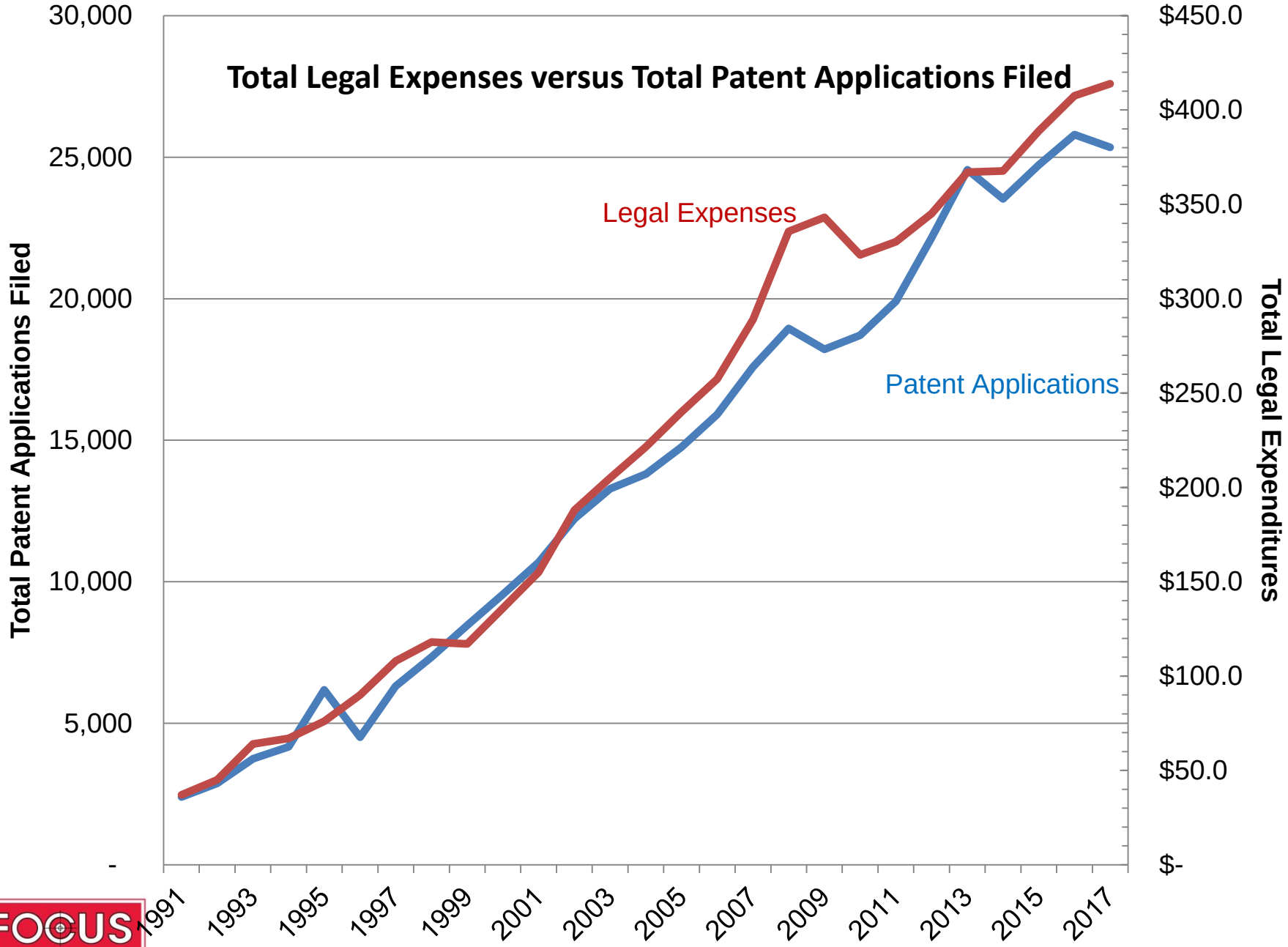
FOCUS IP GROUP, LLC



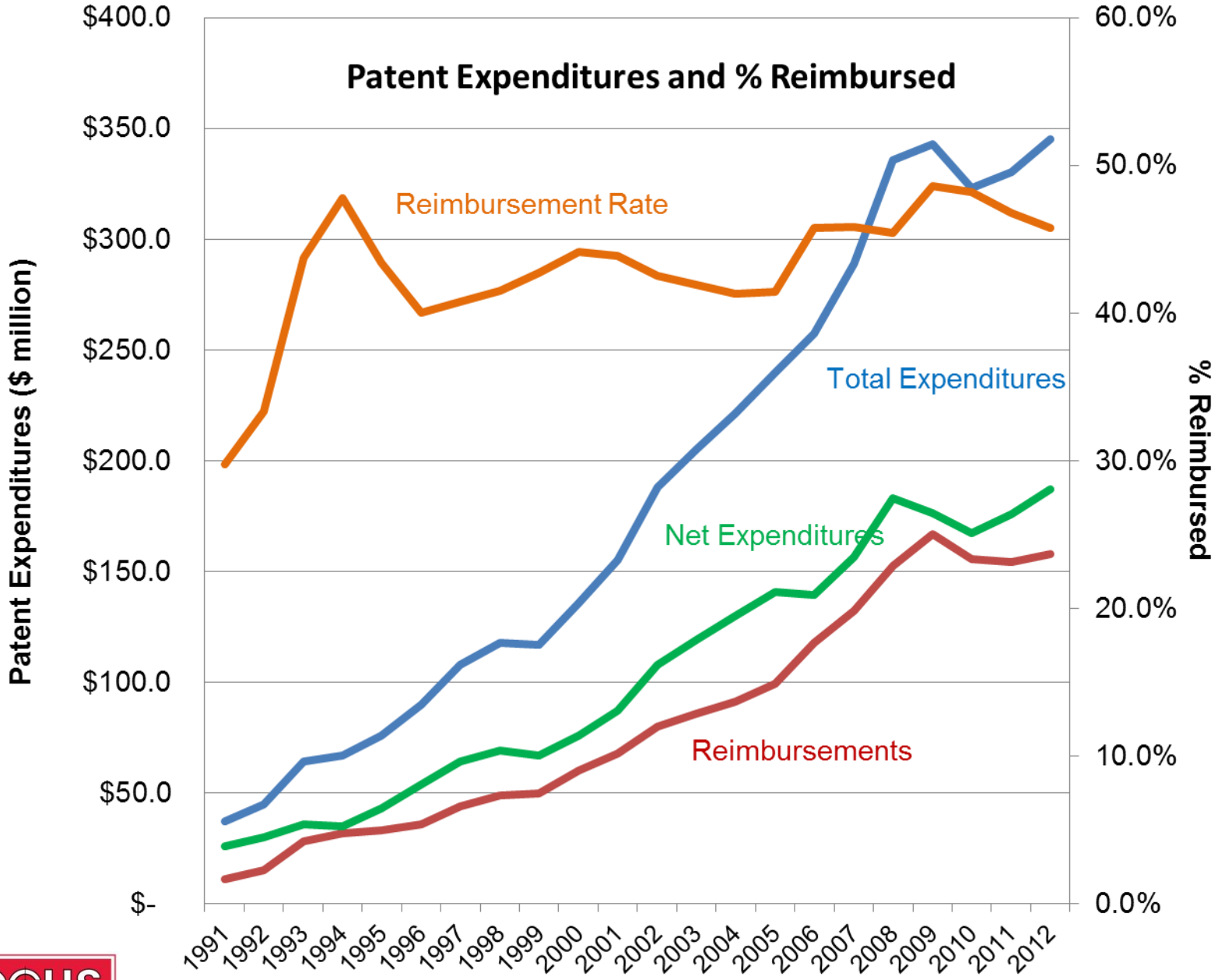
FOCUS IP GROUP, LLC



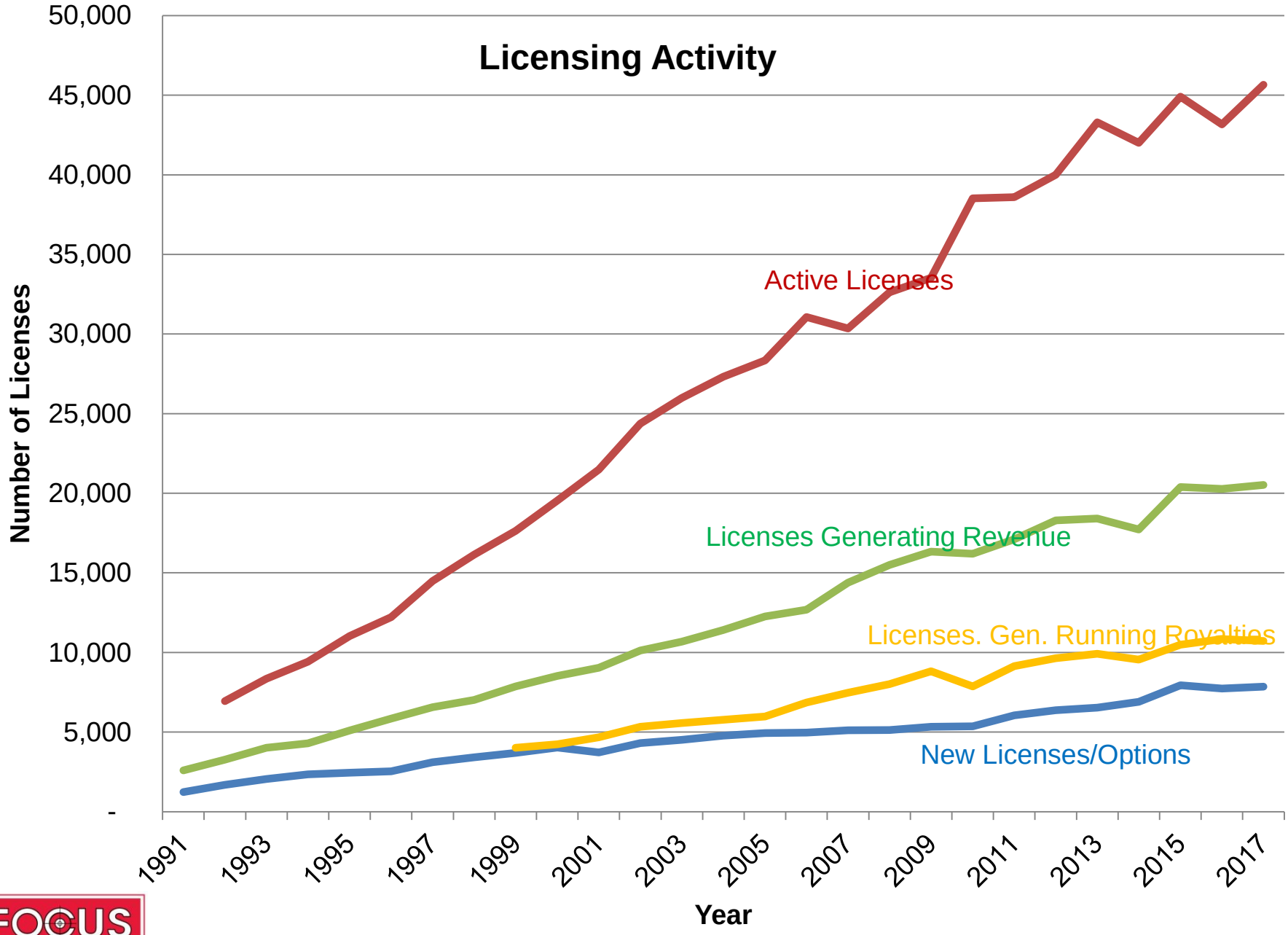
FOCUS IP GROUP, LLC



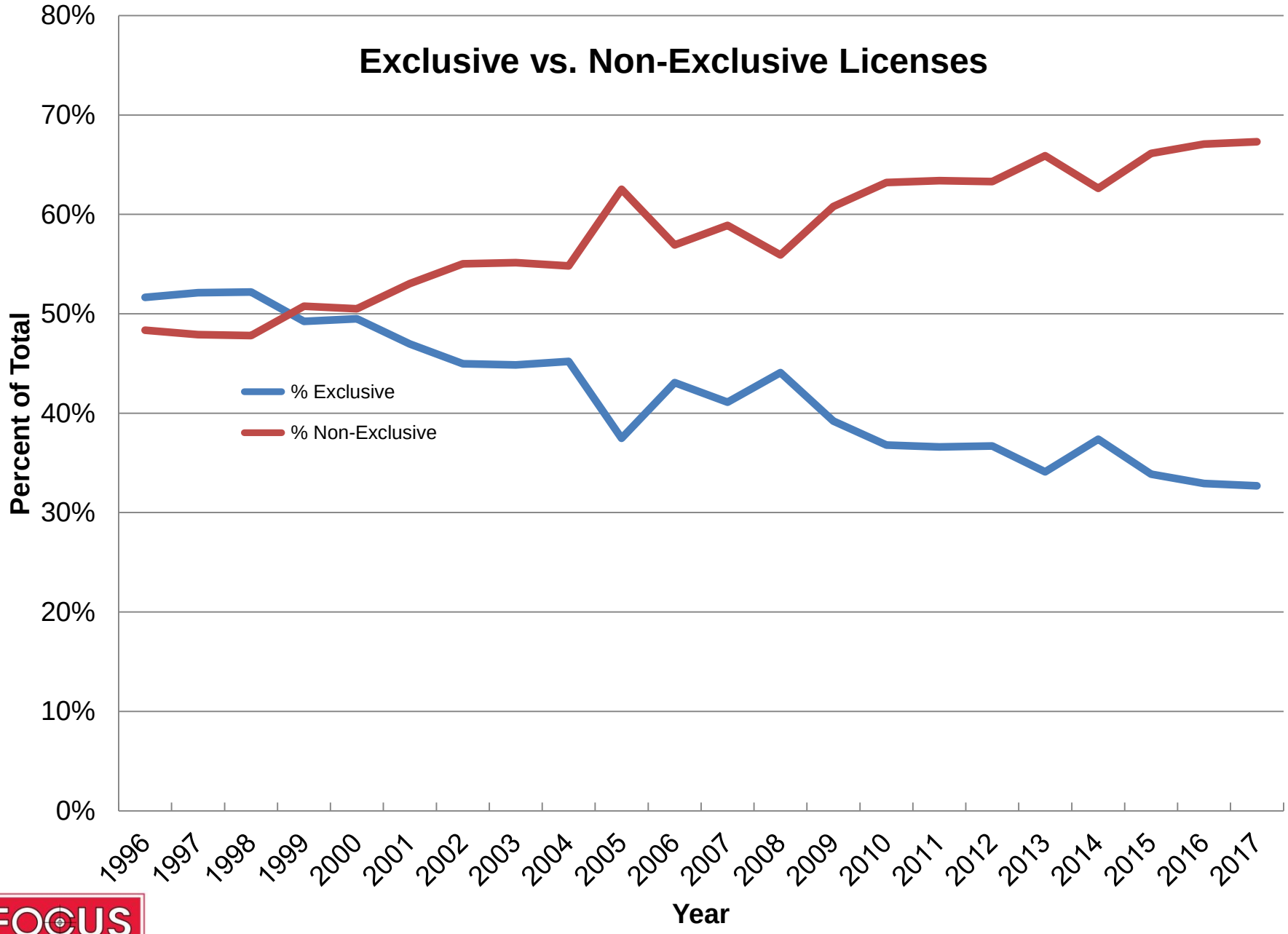
FOCUS IP GROUP, LLC



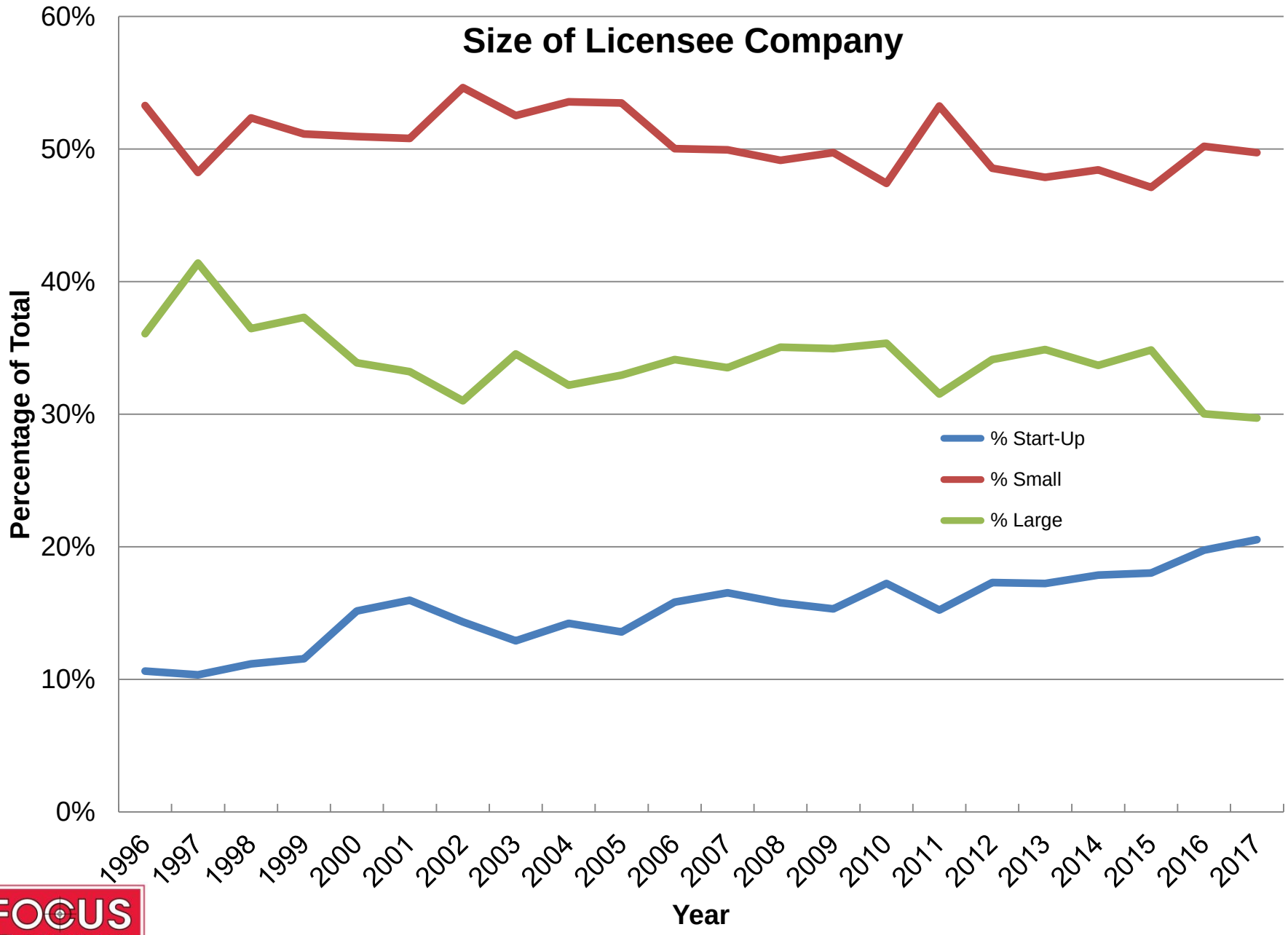
FOCUS IP GROUP, LLC



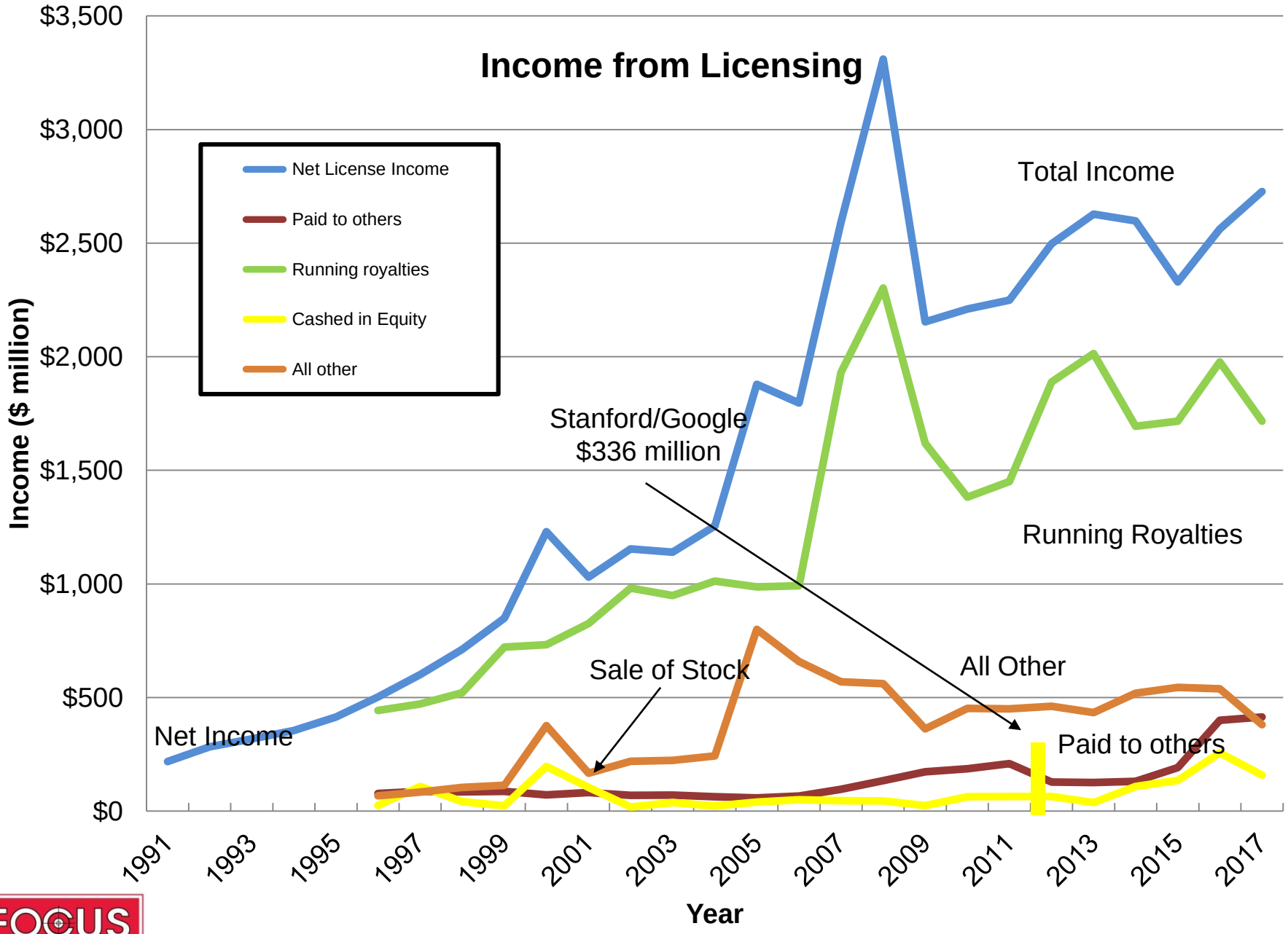
FOCUS IP GROUP, LLC



FOCUS IP GROUP, LLC



FOCUS IP GROUP, LLC

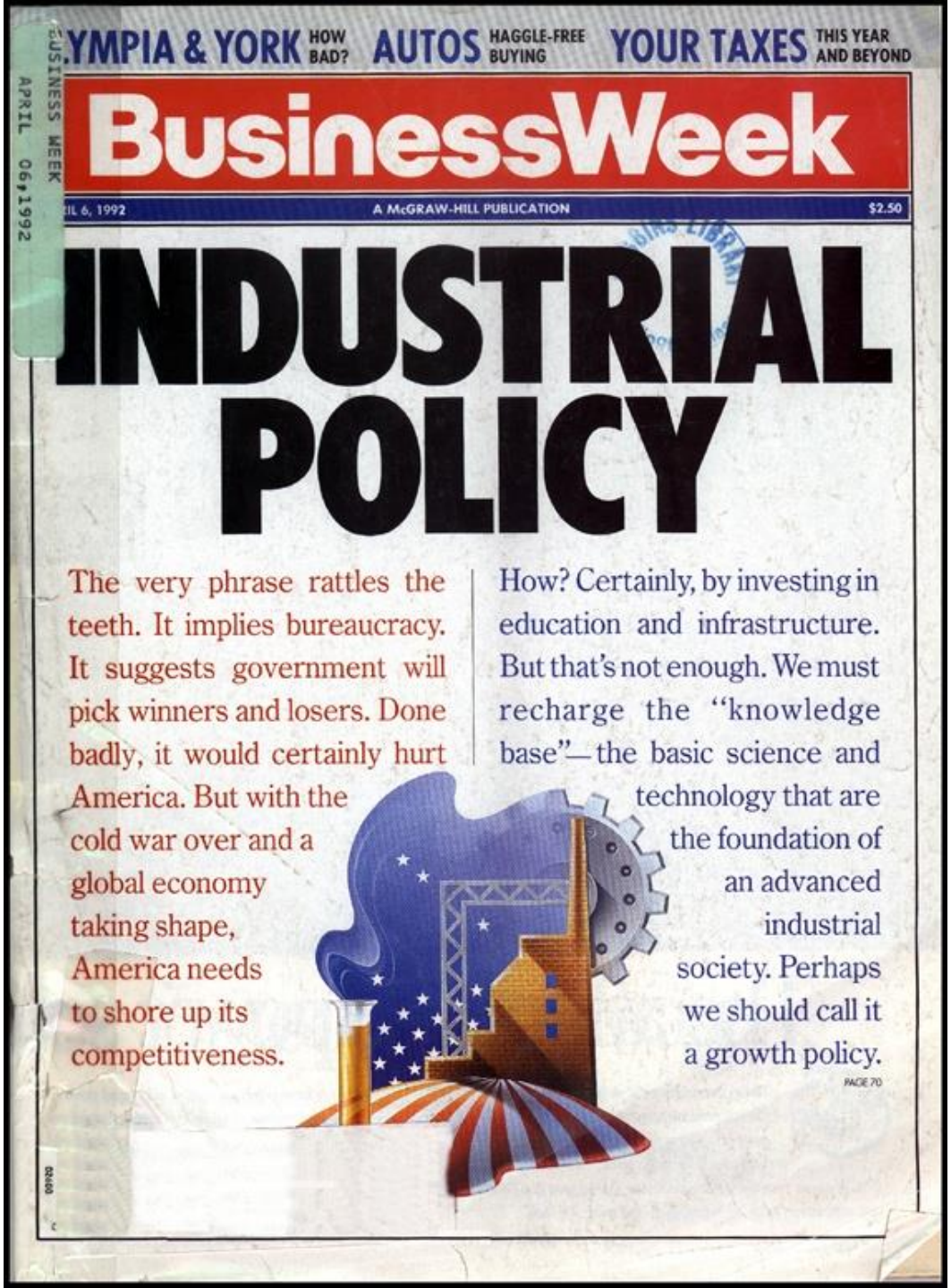


Academic Technologies Have the Power to Transform Economies

- 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

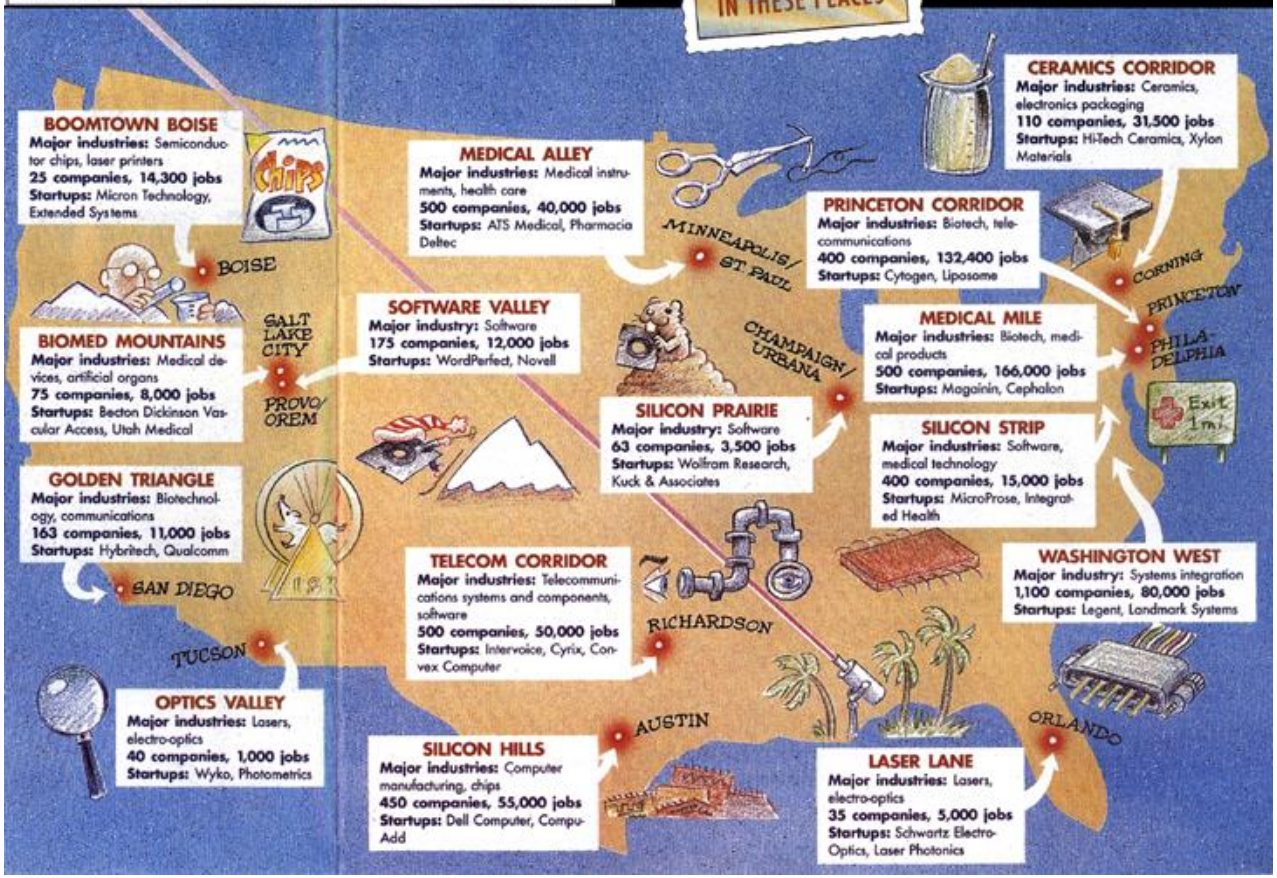

YMPIA & YORK HOW BAD?
AUTOS HAGGLE-FREE BUYING
YOUR TAXES THIS YEAR AND BEYOND
BusinessWeek
IL 6, 1992
A McGRAW-HILL PUBLICATION
$2.50
INDUSTRIAL POLICY
The very phrase rattles the teeth. It implies bureaucracy. It suggests government will pick winners and losers. Done badly, it would certainly hurt 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

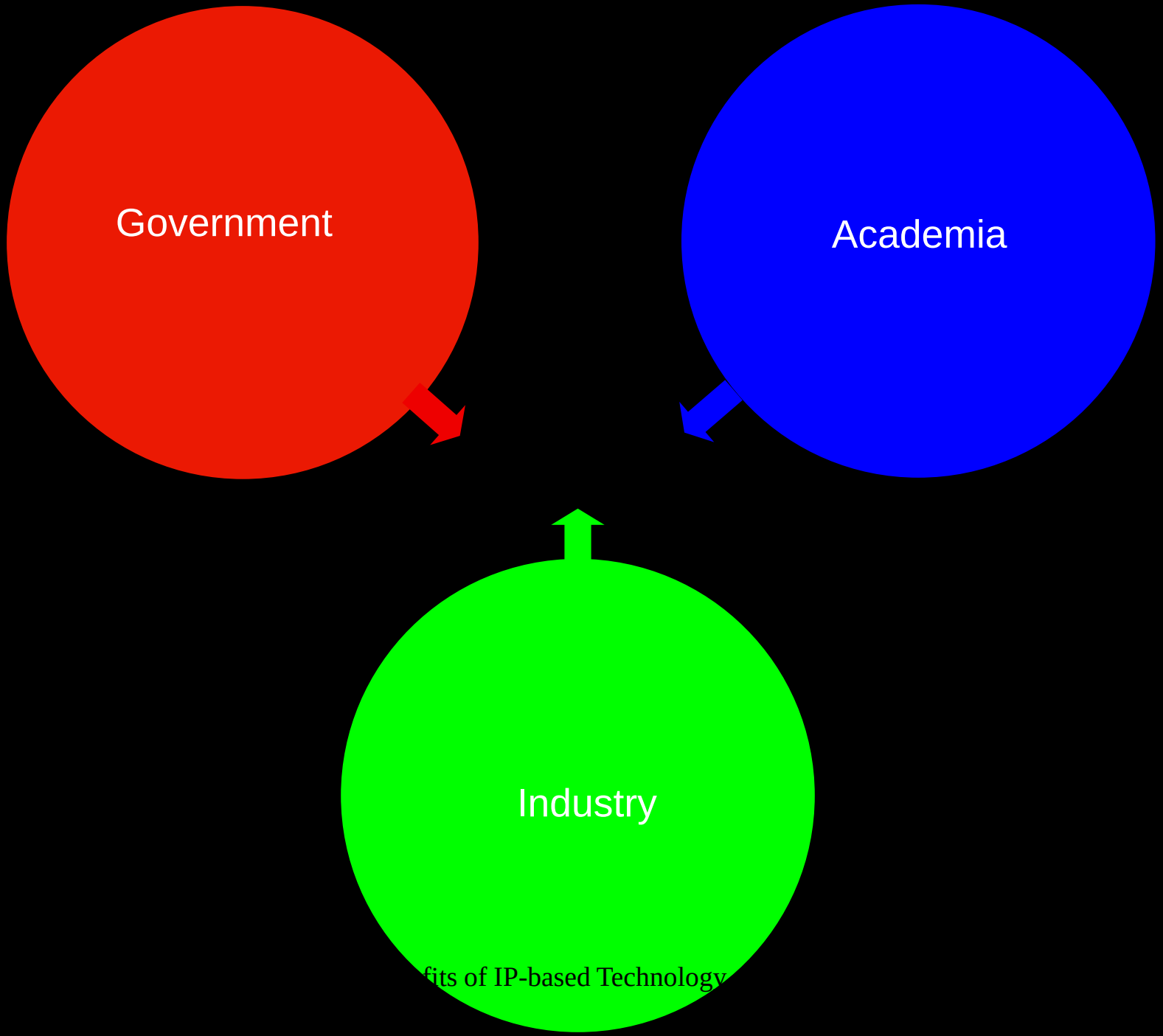
Phases of Economic Development

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

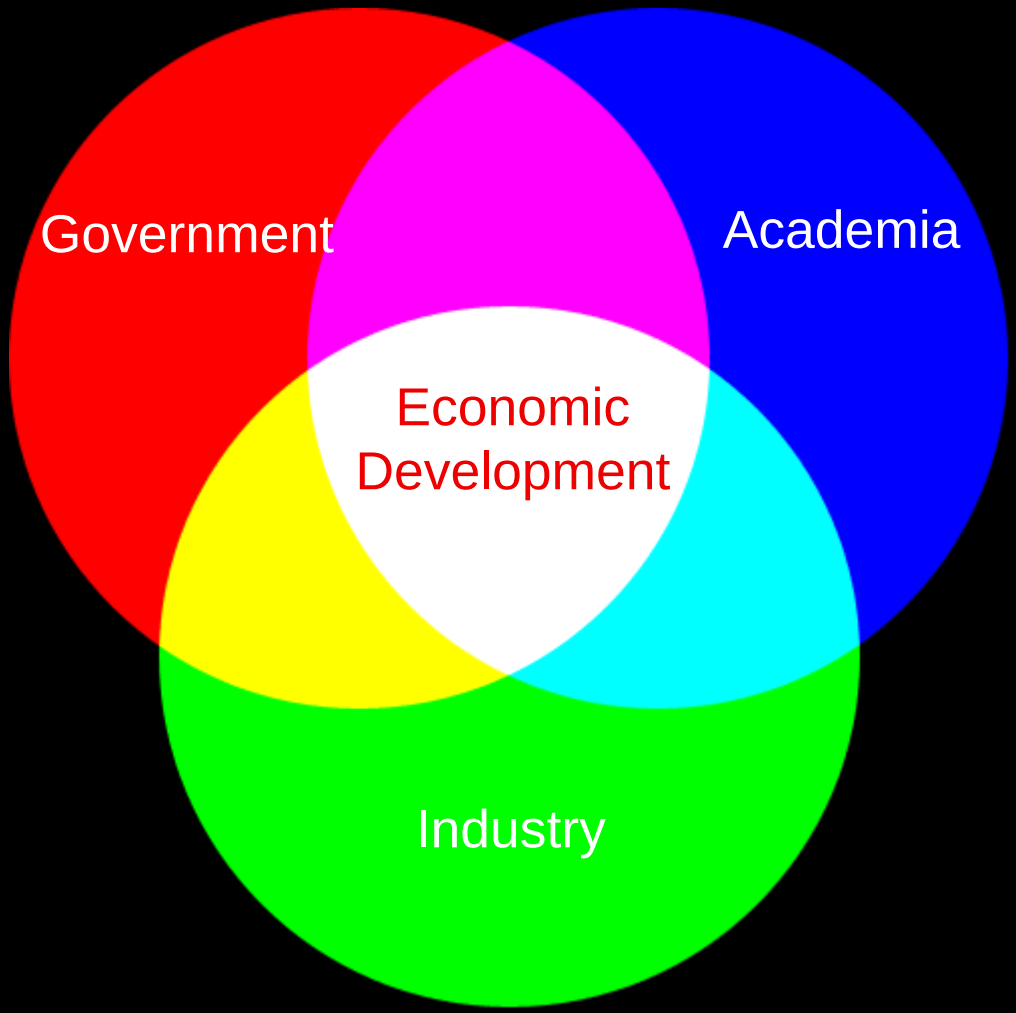
FOCUS IP GROUP, LLC

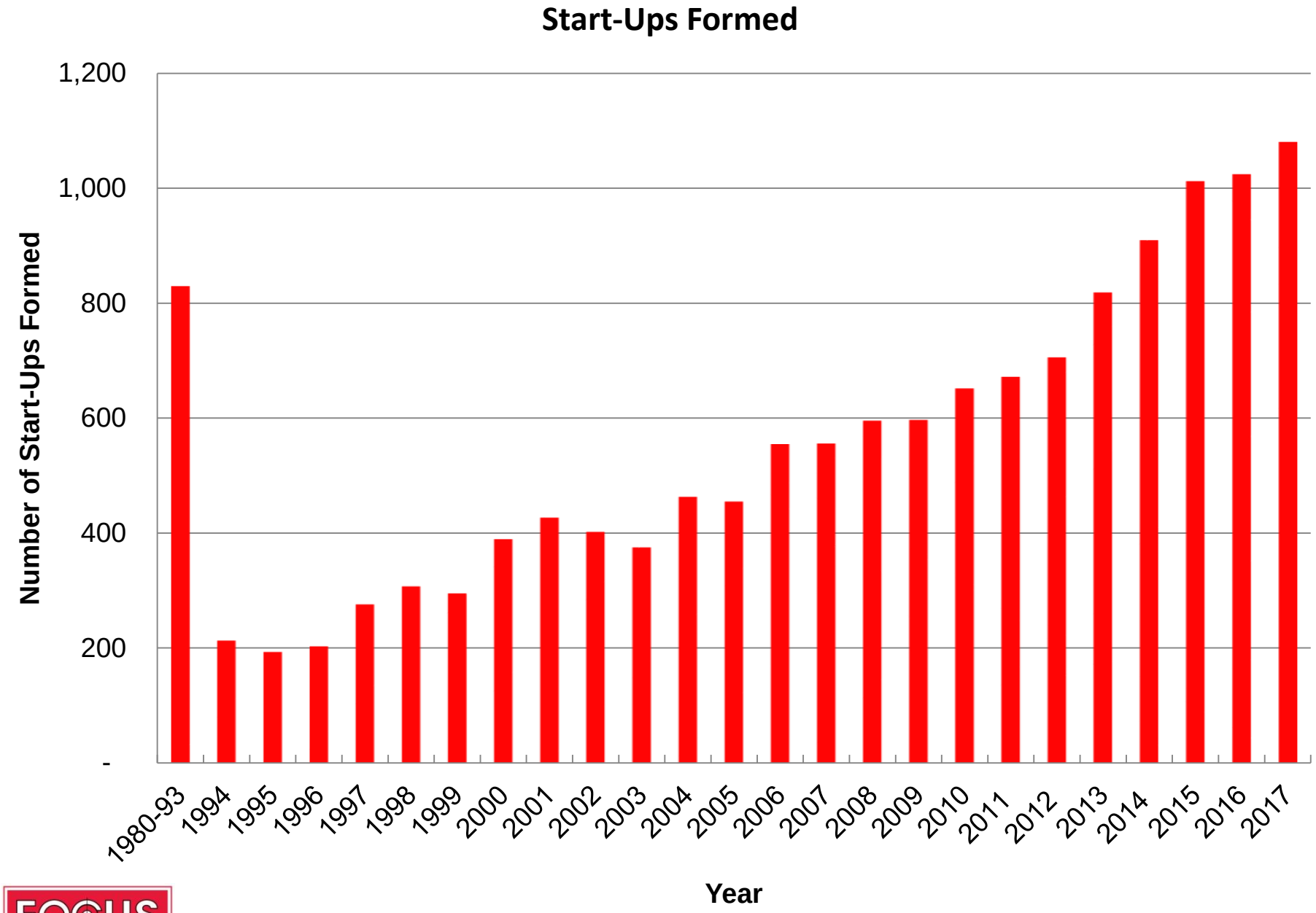
The “Triple Helix” model of Economic Development

FOCUS IP GROUP, LLC



fits of IP-based Technology


Government
Academia
Economic
Development
Industry



FOCUS IP GROUP, LLC

Start-Up Companies

- 13,085 formed 1980-2017
  - 72.4% located in same state as institution
    - Every state
      - 12.3% from California institutions*
      - 11.8% from Massachusetts institutions*
      - 363 by MIT*
      - 349 by University of California System*
      - 175 by University of Utah*
  - 43.3% still active in 2017

AUTM Annual Licensing Activity Survey 1994-2012

* Through 2010

FOCUS IP GROUP, LLC

100 SUCCESS STORIES

GOVERNMENT FUNDING

+

UNIVERSITY RESEARCH

=

INNOVATION, COMPANIES, JOBS

SPARKING ECONOMIC GROWTH

How federally funded university research creates innovation, new companies and jobs

THE SCIENCE COALITION

APRIL 2010

www.sciencecoalition.org

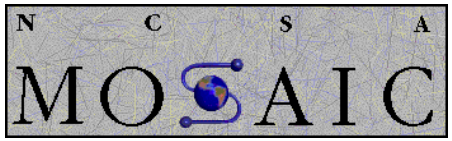
Two Areas of Particular Impact

- 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

- 357 FDA approved drugs, biologics, vaccines and *in vivo* diagnostics[1]

U.S.	242
Non-U.S.	72
Both	43
	357

[1] Unpublished data A.J. Stevens, A. J., and M. Rohrbaugh

FOCUS IP GROUP, LLC

Discovering Countries

Country	No. of Drugs	%
US	285	66.6%
Canada	22	5.1%
UK	20	4.7%
Germany	18	4.2%
Belgium	15	3.5%
Japan	14	3.3%
Australia	13	3.0%
Czech Republic	12	2.8%
Israel	12	2.8%
France	8	1.9%
Sweden	4	0.9%
Switzerland	1	0.2%
China	2	0.5%
Holland	1	0.2%
Russia	1	0.2%
Total	428	

FOCUS IP GROUP, LLC

Number of Products

	Number
New Chemical Entity	231
Biologic	75
Vaccine	22
Over the counter	2
NCE / OTC	2
In-vivo diagnostic	25
Total	357

FOCUS IP GROUP, LLC

Therapeutic Categories

Therapeutic Area	Number	%
Oncology	85	23.8%
Infectious Disease	68	19.0%
Metabolic	48	13.4%
CNS	45	12.6%
Cardiology	22	6.2%
Renal	14	3.9%
Dermatology	14	3.9%
Gastroenterology	12	3.4%
Women's Health	11	3.1%
Ophthalmology	9	2.5%
Immunology	7	2.0%
Anaesthesiology	6	1.7%
Pulmonary	5	1.4%
Urology	4	1.1%
Allergy	2	0.6%
Dental	2	0.6%
Emergency Medicine	2	0.6%
Otolaryngology	1	0.3%
Total	357	

FOCUS IP GROUP, LLC

Discovering Institutions

Institution	Number
National Institutes of Health	27
U. of California	21
Emory University	19
KU Leuven	14
Czech Academy of Sciences	12
Hans-Knoell-Institute Jena	10
Tufts Medical Center	10
Tufts University	10
U. of Toronto	10
Columbia University	9
Memorial Sloan Kettering	9
U. of Texas	9
Individual	8
Massachusetts General Hospital	8
Weizmann Institute	8

FOCUS IP GROUP, LLC

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, Vertex
    - Some stumbled and were acquired
      - Genetics Institute➔AHP ➔Wyeth-Ayerst ➔Pfizer
    - Some succeeded and were still acquired
      - Genzyme ➔Sanofi
  - Massachusetts Biotechnology Research Park
    - Next to University of Massachusetts Medical Center
    - BASF first big pharma to move in
      - Discovered and developed Humira®
        - Top selling drug in the world -- $20 billion

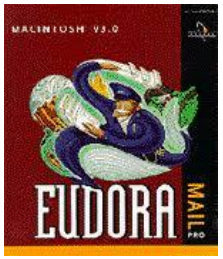
FOCUS IP GROUP, LLC


Biogen
gsk
GlaxoSmithKline
Alkermes
Roche
ALGETA
Celgene
Takeda
AMGEN
ARIAD
IMMUNOGEN, INC.
Eisai
AsahiKASEI
AstraZeneca
DSM
SUNOVION
Healthy bodies, healthy lives
Bristol-Myers Squibb Company
Lilly
Ironwood
ENANTA Pharmaceuticals
AMAG PHARMACEUTICALS
MERCK SERONO
SERVIER
MERCK Research Laboratories
abbvie
KERYX
sanofi aventis
L'essentiel c'est la santé.
Shire
IPSEN
Innovation for patient care
pSivida corp
MERRIMACK PHARMACEUTICALS
Baxalta
Johnson & Johnson
BIOMARIN
Aegerion Pharmaceuticals
VERTEX
Pfizer
NOVARTIS

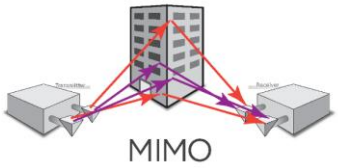
Other Major Products Invented in Academia

Akamai

Google



Lex Machina™
a LexisNexis® Company



FireEye

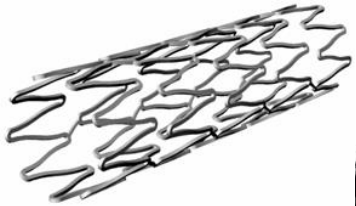
Oculus

vmware

DVD™

RSA

Blu-ray Disc™



Blue LED

A Cautionary Final Note

- Technology transfer from academic institutions can have a big impact on a country's economy
- **BUT** this doesn't necessarily translate to the activity being profitable for the university:
  - If a tech transfer office gets a 5% royalty
    - Or owns 5% of a start-up company that gets sold
  - It's doing a really great job
  - **BUT THAT MEANS THAT 95% OF THE ECONOMIC IMPACT IS OUTSIDE THE UNIVERSITY**
    - In the private sector
      - Which had to finance the development of the university invention
    - Tech transfer may benefit the country but be a net cost to individual universities
      - And university Presidents hate net costs!

FOCUS IP GROUP, LLC

A Cautionary Final Note

- Which is why governments should support tech transfer at their universities
  - It should be considered part of the country's core economic infrastructure
    - Like airports, railways, roads, internet etc.
- Support particularly important in the early stages
  - Typically for 10 years
    - Canada, Denmark, France, Japan, UK, Chile
- Many of the inventions that come from emerging country economies target local problems, opportunities and issues

FOCUS IP GROUP, LLC

Thank you for listening

Questions?

astevens@bu.edu

FOCUS IP GROUP, LLC