Moffitt Cancer Center Strategic Retreat

Why Do We Do What We Do?

Tampa, FL
March 20, 2018

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

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We've decided to rebrand the Technology Transfer Office. You're now the Office of Technology Licensing and Commercialization, Venture Creation, Industry Liaison, Economic Development and Societal Impact

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The Many Missions of Universities

- To teach existing knowledge to the next generation
  - While helping them to transition from adolescents to adults
- To discover new knowledge and disseminate it broadly
  - While training the next generation of researchers
- To care for patients
  - While advancing medical care
- To be a source of economic development
  - While not conflicting with the previous three elements of their Mission!
  - The newest of the missions

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What Are the Benefits of Technology Transfer?

- Economic development
  - Being seen to benefit the regional and national economies
    - ➔ Increased government support
- Reputational
  - Enhancing entrepreneurship regionally and nationally
    - ➔ Increased government support
- Student recruitment
  - This generation of students is highly entrepreneurial
- Financial
  - Corporate support
  - Faint possibility of financial return from licenses and spin-outs

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What Drives Technology Transfer In Your Institution?

- Why are you doing technology transfer?
  - To make money?
  - To indulge faculty?
  - To disseminate the results of your research?
  - To benefit society?
  - To develop the local economy?
  - Help – I just needed a job?
- Management's response is often "Yes"
  - Do them all
    - *You're now the Office of Technology Licensing and Commercialization, Venture Creation, Industry Liaison, Economic Development and Societal Impact*
- We need to ask "Can you do them all?"
  - Or are there trade-offs?

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Operating Models for Technology Transfer

- Faculty Service
  - Support the creative and entrepreneurial aspirations of faculty and graduate students
    - And undergraduates?
- Revenue Maximization
  - Generate the maximum amount of license income
- Knowledge Transfer
  - Licensing, Sponsored Research, Faculty Consulting
- Economic Development
  - Maximize job creation / retention
    - Regionally
    - Nationally
- Societal Benefit
  - Meet the needs of society that market forces will not meet

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Faculty Service

- Supporting the entrepreneurial aspirations of faculty
- Faculty are inherently entrepreneurial
  - Each lab is an independent research enterprise
    - Each PI has to “sell” his / her research
      - To raise grant funding
      - To secure a flow of the best grad students and post-docs

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Faculty Service

- The transition to commercialization is an easy next step
  - “One Day per Week” consulting rules allow faculty to be active in commercialization and stay at the university
  - Often most active post-tenure.
- Graduate students are at a stage in their life where they can take risks
  - Used to working all hours
  - Great carriers of the technology from the university to industry

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Nobody Should Force Faculty to Commercialize

- It's their choice to participate
  - Nobody can force faculty to do anything they don't want to!
- The Institution's role is to make it easy for them to commercialize
- Patents may seem to be anathema to academic freedom
  - Locking people out versus open dissemination
- The role of a patent is to give control over how discoveries are commercialized
  - And by whom

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Culture

- Commercialization often a new concept
  - Many in university will feel commercialization isn't a proper role for academics
    - Feel they should be
      - Teaching
      - Researching
        - Getting grants
        - Graduating Ph.D. students
  - Important that academic management be seen to support and endorse commercialization
- Essential that participation be voluntary
  - Institution's job is to facilitate the process for those who chose to do it

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Culture

- Most faculty DON'T participate in the technology transfer process[1]

Career Disclosures	%
Never	64.2
Once	14.8
Twice	7.6
Three to five	11.4
Six or more	2.0

1 Thursby, J. G. and M. C. Thursby (2003). Patterns of Research and Licensing Activity of Science and Engineering Faculty. Working Paper. Atlanta, GA, Georgia Institute of Technology., available at: http://hdl.handle.net/1853/10723

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But the Best Scientists Do

Nobel Prize Winners* with Patents	%
Physics	44%
Chemistry	77%
Physiology or Medicine	78%

* Winners of Nobel Prize from 2001 to 2013

Source: Qingzhi Zhang, Collette LaFlamme, Trent Merrell and Ashley J. Stevens, Unpublished Data

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The Traditional Scientific Paradigm

The academic dissemination route

The commercial dissemination route

The New Scientific Paradigm

- The “Patent-Paper-Pair”
  - Fiona Murray, MIT
    - 50% of papers in *Nature Biotechnology* 1997-1999 had a corresponding patent[1]
  - 33% of biotech papers in *Science* and *Nature* had a corresponding patent[2]

1 Murray, F., Stern, S., Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis, *Journal of Economic Behavior and Organization* (2007), doi:10.1016/j.jebo.2006.05.017

2 Lebovitz, R. M. (2007). "The Duty to Disclose Patent Rights." Northwestern Journal of Technology and Intellectual Property **6 (Fall 2007)**: 36-45.

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Has The Nature Of Academic Research Been Changed?

- Publication rate doubled over course of study
- Disclosure rate went from 1% to 10% of faculty per year
- No change in “basic” vs. applied” balance of research, as measured by journals published in

Thursby and Thursby, ibid

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So Why Do Faculty Commercialize Their Science?

- It's highly satisfying to see science have an impact beyond academia
  - Giving back to society
- It can bring additional resources into their scientific enterprise
  - New funding
  - Access to new technical capabilities
  - New collaborators
- It can create new avenues of research
  - Identify new problems that need to be solved
- It can create job opportunities for the students
  - Existing companies
  - Start-up companies
- And, finally, they may just get really, really rich

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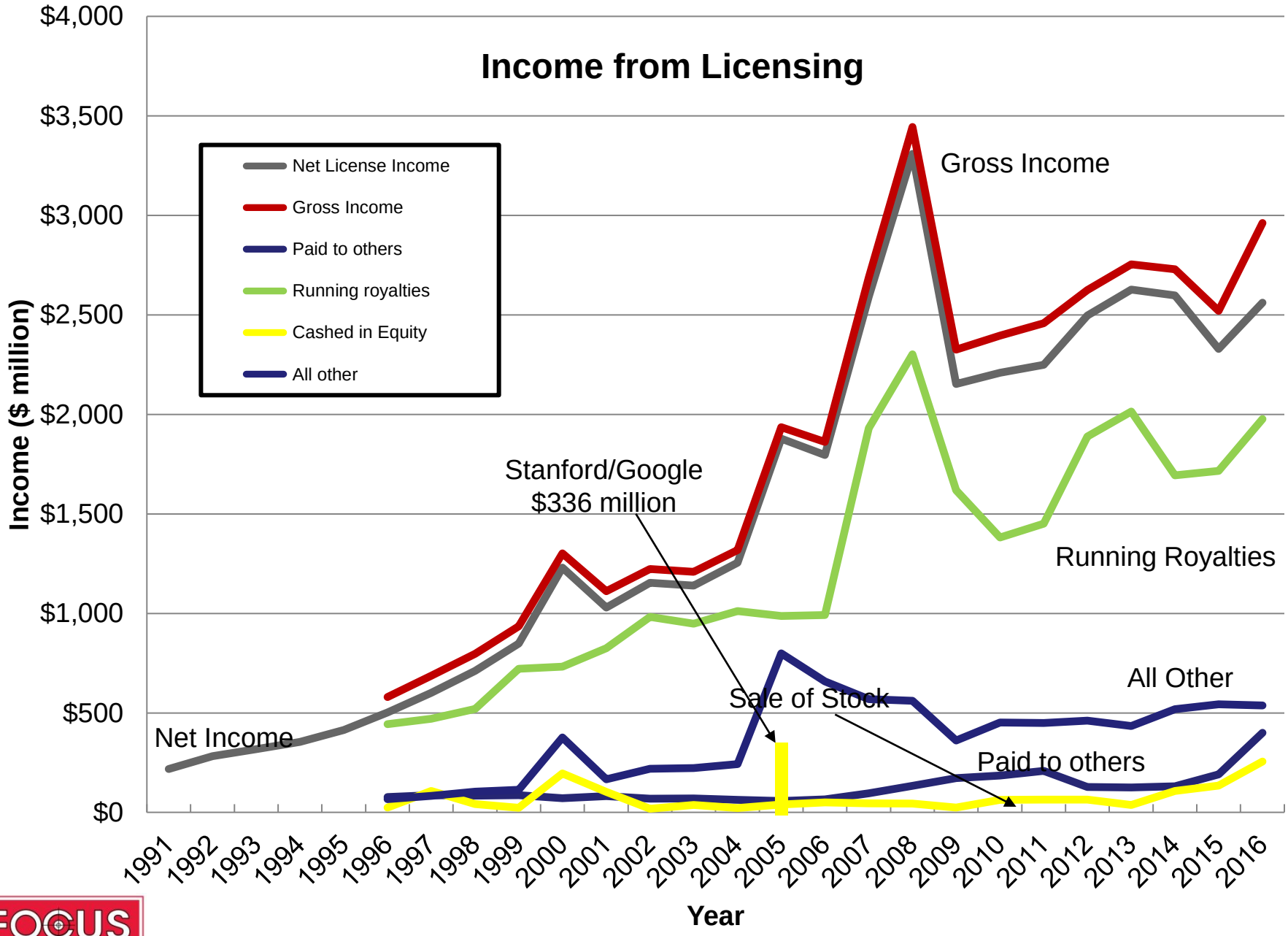
Generating Revenue



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Revenue

- Some institutions have made game changing amounts from tech transfer:
  - City of Hope (Riggs-Itakura, Insulin, hGH, Cabilly) $3.7 billion
  - Columbia (Axel, Functional Antibodies, MPEG, Xalatan®) $2.9 billion
  - Northwestern University (Lyrica®) $2.9 billion
  - UCLA (Xtandi®) $1.4 billion
- And a few professors have got really, really rich
  - Shmuel Cabilly (City of Hope), Synthetic antibodies
  - Richard Silverman (Northwestern), Lyrica:
    - 25% * $2 billion = $500 million!
- But most don't*
  - Active licenses 43,165
  - Licenses generating income 20,269
  - Licenses generating running royalties 10,846
  - Licenses generating more than $1 million 217

* AUTM 2016 Survey

The Business of Technology Transfer

- A horrible 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
    - An average of 4 years from disclosure to license
  - 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 patents to expire

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The Bottom Line – Red Ink

Financial Contribution	Number	%
Loss making		
Gross profitable		
Net profitable		
Self sustaining		
Total		

Source: Abrams, Leung & Stevens, 2010

Knowledge Transfer

Knowledge Transfer

- Focuses on engaging industry more broadly than just licensing
- Exploiting know-how as well as patents
  - Industrial research support
  - Faculty consulting
- Creates a much bigger revenue base
- Largely a European model
  - In U.S., OTT's generally separate from Sponsored Programs
    - Some OTT's do handle industrial sponsored research agreements
  - Consulting generally a faculty prerogative
    - Generally not subject to institutional oversight
- Some U.S. universities don't even include know-how in license agreements
  - E.g., MIT, Stanford, U. California system

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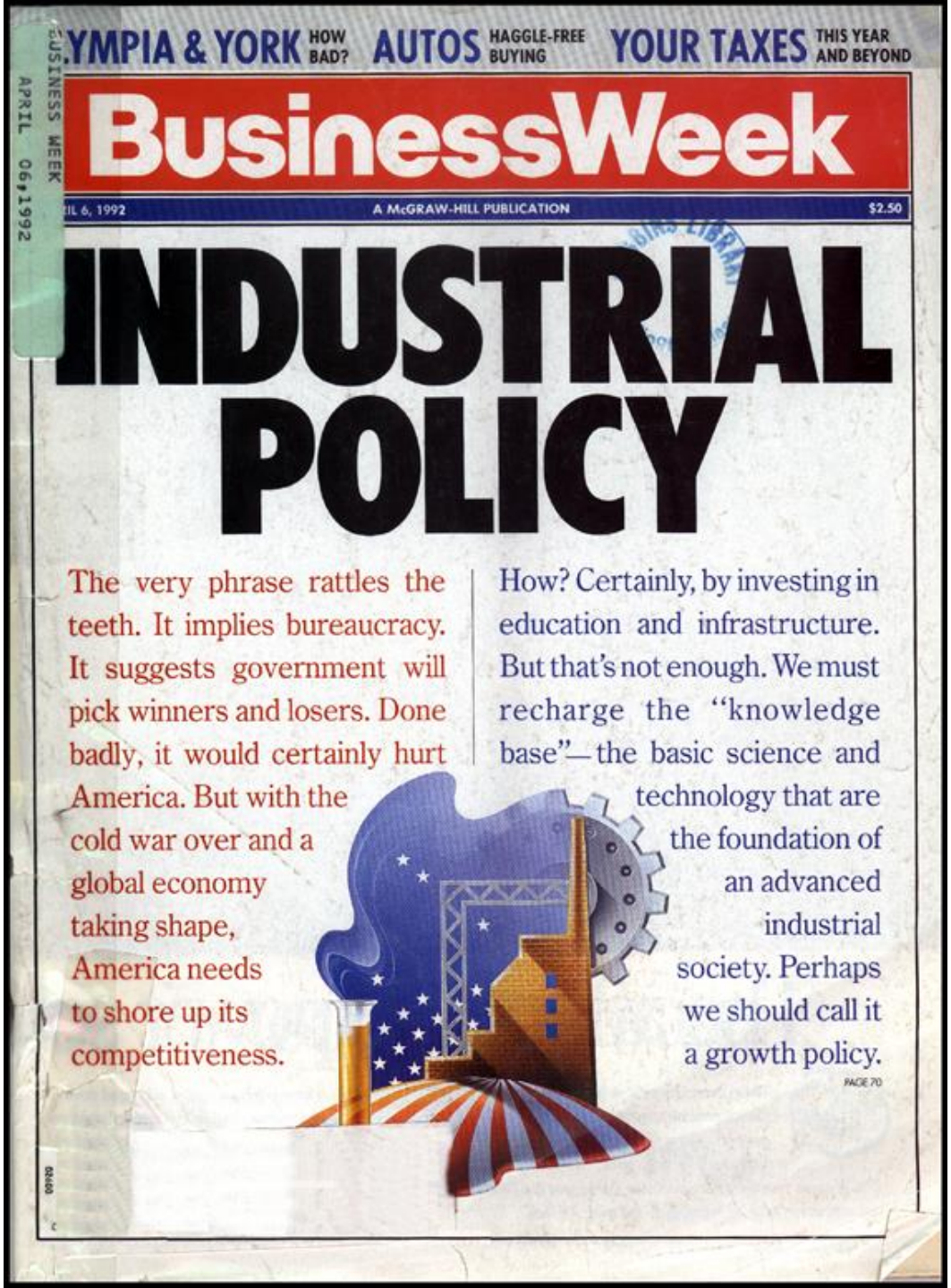
Economic Development

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
BOOMTOWN BOISE
Major industries: Semiconductor chips, laser printers
25 companies, 14,300 jobs
Startups: Micron Technology, Extended Systems
BOISE
BIOMED MOUNTAINS
Major industries: Medical devices, artificial organs
75 companies, 8,000 jobs
Startups: Becton Dickinson Vascular Access, Utah Medical
SALT LAKE CITY
PROVO/OREM
GOLDEN TRIANGLE
Major industries: Biotechnology, communications
163 companies, 11,000 jobs
Startups: Hybritech, Qualcomm
SAN DIEGO
TUCSON
OPTICS VALLEY
Major industries: Lasers, electro-optics
40 companies, 1,000 jobs
Startups: Wyko, Photometrics
MEDICAL ALLEY
Major industries: Medical instruments, health care
500 companies, 40,000 jobs
Startups: ATS Medical, Pharmacia Deltec
MINNEAPOLIS/ ST PAUL
SOFTWARE VALLEY
Major industry: Software
175 companies, 12,000 jobs
Startups: WordPerfect, Novell
CHAMPAIGN/ URBANA
SILICON PRAIRIE
Major industry: Software
63 companies, 3,500 jobs
Startups: Wolfram Research, Kuck & Associates
TELECOM CORRIDOR
Major industries: Telecommunications systems and components, software
500 companies, 50,000 jobs
Startups: Intervoice, Cyrix, Convex Computer
RICHARDSON
AUSTIN
SILICON HILLS
Major industries: Computer manufacturing, chips
450 companies, 55,000 jobs
Startups: Dell Computer, CompuAdd
CERAMICS CORRIDOR
Major industries: Ceramics, electronics packaging
110 companies, 31,500 jobs
Startups: Hi-Tech Ceramics, Xylon Materials
PRINCETON CORRIDOR
Major industries: Biotech, telecommunications
400 companies, 132,400 jobs
Startups: Cytogen, Liposome
CORNING
PRINCETON
PHILADELPHIA
MEDICAL MILE
Major industries: Biotech, medical products
500 companies, 166,000 jobs
Startups: Magainin, Cephalon
Exit 1mi
SILICON STRIP
Major industries: Software, medical technology
400 companies, 15,000 jobs
Startups: MicroProse, Integrated Health
WASHINGTON WEST
Major industry: Systems integration
1,100 companies, 80,000 jobs
Startups: Legent, Landmark Systems
ORLANDO
LASER LANE
Major industries: Lasers, electro-optics
35 companies, 5,000 jobs
Startups: Schwartz Electro-Optics, Laser Photonics

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 lead growth

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Ingredients of a High Tech Cluster

- **A major research university**
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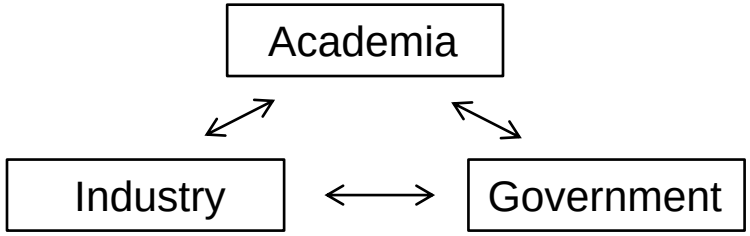
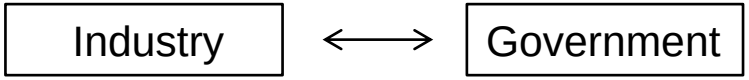
The Triple Helix Model of Economic Development

- First description of the Triple Helix* model of economic development



- As opposed to the traditional bilateral model



* Henry Etzkowitz, 1992

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
      - Genzyme ➔ Sanofi
  - Massachusetts Biotechnology Research Park
    - Next to University of Massachusetts Medical Center
    - BASF first big pharma to move in (1990)
      - Discovered and developed Humira®
        - World's top selling drug


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

Other Measures of Economic Impact

- Can estimate sales of licensed products
  - $100 billion in U.S.
- Can look at employment and sales of university spin-out companies
  - E.g., Alphabet (Google)
    - $790 billion market cap
    - $90 billion in sales
    - 79,000 employees

So, If It's Such A Big Deal, Why Don't People Make Money?

- The major impact of technology transfer is external
- If a technology transfer officer negotiates a 5% royalty or a 5% equity stake at IPO, they're doing a god job
  - But that means 95% of the economic impact is external to the University
  - Where it should be because private investment is needed to turn an embryonic academic discovery into a successful product
    - Often a massive investment

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Economic Development Is More Than Just Start-Ups

- Don’t forget existing companies
  - Important for universities to support existing companies as well as start-ups
    - More immediate impact
      - Many more employees than startups
    - Political visibility
  - Company-friendly sponsored research philosophies
    - E.g., U. of Minnesota / Penn State fully paid up license approaches
  - Regional cooperation
    - Florida High Tech Corridor

TECHNOLOGY TRANSFER EVOLUTION:

DRIVING ECONOMIC PROSPERITY

Report of the Technology Transfer Evolution Working Group of APLU's Commission on Innovation, Competitiveness & Economic Prosperity (CICEP)

NOVEMBER 2017

ASSOCIATION OF PUBLIC & LAND-GRANT UNIVERSITIES

Societal Benefit

- The majority of licenses don't generate much revenue
  - But some can generate enormous societal benefit
- Biggest example – The Internet
  - World Wide Web invented at CERN, Geneva
    - Given away free
  - Enabling technologies
    - First web browser

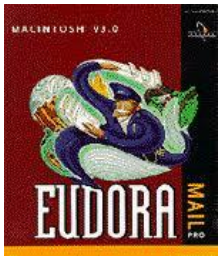
    - First email program that could attach documents

invented at University of Illinois Urbana-Champaign

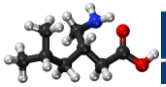
  - Made maybe $8-10 million

Akamai

Google



GARDASIL 9
Human Papillomavirus
9-valent Vaccine, Recombinant



LYRICA
PREGABALIN

Lex Machina™
a LexisNexis® Company

Enbrel
etanercept

Xalatan

Bigliani/Flatow®
The Complete
Shoulder
Solution TSA
Surgical Technique

FireEye

Remicade®
INFLIXIMAB

vmware

RSA

COUMADIN®
(Warfarin Sodium Tablets, USP) Crystalline
1mg 2mg 2.5mg 3mg 4mg 5mg 6mg 7.5mg 10mg

DVD

Blu-ray Disc™

Oculus

duolingo

Gatorade®

Blue LED

Societal Benefit

- The only model in the U.K.
  - Consequence of evolving government evaluation frameworks of university research excellence
    - Demanded to know the impact of research it funded
    - Sophisticated procedures developed to demonstrate impact
      - 20% of research funding now based on impact of past research
    - Australia making the same change

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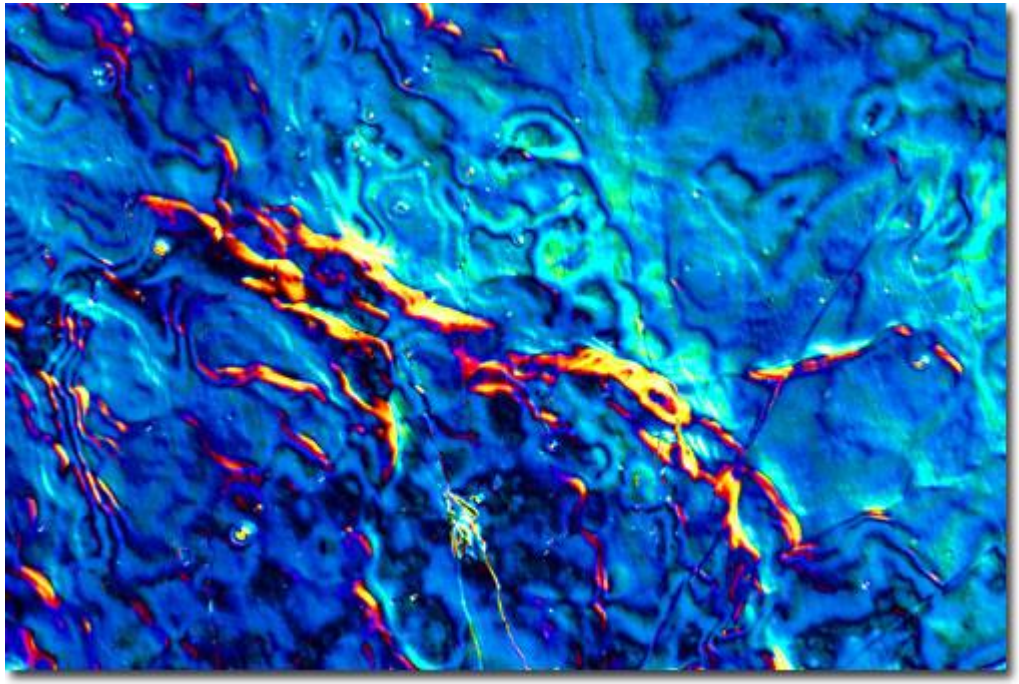
Case Study – Florida State University – MADD



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Case Study: University Licensing Policies and Global Health

- Problem first surfaced in 2001 with Yale and Zerit
- d4T discovered by Drs. Tai-Shun Lin and William Prusoff
- Funded by NIH and Bristol-Myers
- Exclusively optioned then licensed to Bristol-Myers
- On list of Essential Medicines developed by *Medécins Sans Frontieres*
- Requested waiver of S. African patent
- Yale said they were powerless – BMS had an exclusive license

The Zerit/Yale Story

- Enter Amy Kapczynski 

- First year Yale Law Student
- Had met Toby at an AIDS conference in Durban in July 2000
- Toby identified that Yale held the patent and contacted Amy
- She secured support of Prusoff and Michael Merson, Dean of Yale's School of Public Health
  - Former head of WHO HIV/AIDS program

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The Yale Story

- Got a story in the student newspaper March 2, 2001
- Organized a petition
  - Got 600 signatures
- *NYT* ran a story March 11, 2001
- On March 14, 2001 BMS announced it would not enforce the patent in S. Africa and offered to sell d4T for 7.5¢/tablet
- Eventually signed a non-suit to Aspen Pharmaceuticals
- Within a month, Bristol-Myers Squibb, GlaxoSmithKline, Pfizer, Abbott, Hoffman-La Roche, and Boehringer Ingelheim issued a statement promising to lower costs in developing nations
- Lawsuit dropped

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The Challenge for Universities

- How do we ensure that drugs we discover and license are available affordably in emerging countries?
- We could try to change the patent system to achieve this
  - The problem isn't the patent system
  - Patents just give you control over what happens to your IP
  - An essential component of the innovation system
  - We should be very cautious about changing it
    - E.g. PCT Treaty signed 1970
      - Came into effect in 1978
    - Treaty of London (EPO issuances) signed 2000
      - Came into effect 2008
- It's much easier (and less risky!) to change licensing behavior
  - That's a business decision

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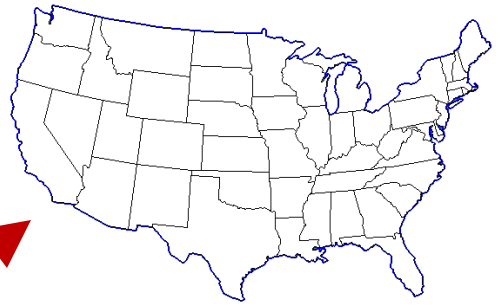
Let's think about how we get a public sector discovered drug to the global market



The Traditional Academic Development Model

How could we modify this process to achieve affordability?

Include Developing Country Milestone and Pricing

Licensee shall seek registration in a developing country by…….

Licensee shall make available in developing countries at prices no more than 50% more than fully burdened manufacturing cost

Don’t Allow Patenting in Developing Countries

Cipla
Caring for life

RANBAXY
LABORATORIES LIMITED

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Separate Licensees

MERCK

Cipla
Caring for life

RANBAXY
LABORATORIES LIMITED

FOCUS IP GROUP, LLC

Mandatory Sublicensing

MERCK

Cipla
Caring for life

RANBAXY
LABORATORIES LIMITED

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Non-Assert

MERCK

Cipla
Caring for life

RANBAXY
LABORATORIES LIMITED

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les Nouvelles

JOURNAL OF THE LICENSING EXECUTIVES SOCIETY INTERNATIONAL

Volume XLIII No. 2 June 2008

So why can't we be the Office of Technology Licensing and Commercialization, Venture Creation, Industry Liaison, Economic Development and Societal Impact?

Because different models have vastly different implications

Implications of Different Operating Models

- Faculty Service
  - Support all invention disclosures received
    - High patent costs
  - Extensive marketing of inventions
    - High personnel costs
  - Don't seek to maximize revenues from every invention
    - Lower income
      - ➔ Profitability not a priority
  - Foster collaborative relationships with industry
    - Access unique industrial capabilities
    - Identify new research opportunities
  - Key Metric: Faculty satisfaction
    - Faculty recruitment

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Implications of Different Operating Models

- Revenue Maximization
  - Selectivity in inventions pursued
    - Try to "pick winners"
      - Reject / give back to inventors inventions with low income potential
  - Extensive marketing
    - Objective is to get multiple bidders for each technology

"A hot academic technology is one two companies are interested in"

Lita Nelsen, MIT

  - Bonus plan for TLO officers based on income
  - Key Metric: Profitability

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Implications of Different Operating Models

- Knowledge Transfer
  - Licensing not sole / primary focus
    - Sponsored research
    - Consulting
    - Organizational issues
  - "Easy Access IP" may be an option
    - Give most IP away for free to start-ups
      - Promote economic development
      - Get return from consulting, collaborative research
  - Financial credit for bigger revenue base
  - Larger staff to handle additional agreements/more complex relationships
  - Key Metric: Technologies in development
    - Public benefit

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Implications of Different Operating Models

- Economic Development
  - Jobs, jobs, jobs
    - "It's the economy, stupid."
  - Less pressure for profitability
    - State/local funding for economic development
      - Incubators
      - Proof of concept
      - Research parks
  - Express Licensing a viable strategy
  - Additional activities
    - Creating funds to invest in start-ups
  - Key Metric: Jobs Created
    - Companies created
    - External investment raised

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Implications of Different Operating Models

- Societal Impact
  - Focus on technologies that can help most people
  - Income / Profitability not a concern
  - Faculties outside of STEM can have major impact
  - Additional activities:
    - Focus on international opportunities
      - Less Developed Countries
      - Philanthropic funding potential
  - Key metrics:
    - People helped

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Organizational Implicaions

- Where should OTT report within the university?
- Depends on Model/Mission chosen
  - Faculty Service — VP for Research
  - Revenue Maximization — VP for Finance
  - Knowledge Transfer — VP for Research
  - Economic Development — VP for Economic Development
  - Societal Impact — VP for Development

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What Drives Technology Transfer in the U.S.?

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	

Source: How US Academic Licensing Offices are Tasked and Motivated – Is it all about the money?", Irene Abrams, Grace Leung and Ashley Stevens, *Research Management Review,* 17.1, Fall/Winter 2009;

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Questions?