The Role of Research Institutions in the Formation of the Biotech Cluster in Massachusetts

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The Massachusetts Biotech Cluster 2005

- Approximately 300 "biotechnology" companies
- Approximately 150 medical device companies
- Top 10 companies total market cap of \$84.5 billion (All of biotech only \$5B in 1991)
- PLUS large research laboratories for 5-8 major pharmaceutical companies
- Employs over 30,000 people

The Formation of Biotech Clusters Contradicts Older Theories

Standard "regional cluster" theory:

Clusters start with a large company

- Suppliers move into the region
- Technology entrepreneurs spin off from the Company into new companies
- Venture capital and other supporters of new companies move into the region
- Management talent moves into the region
- More companies form

Biotech reversed the theory

- The great Biotech clusters of the U.S.—San Diego, San Francisco, Boston--did NOT originate in areas where pharmaceutical companies existed
- The geographical areas with pharmaceutical companies (New Jersey, Chicago, Indianapolis) did NOT spawn many biotech companies
- "Supply chains" for biotech companies have been irrelevant as drivers of new company formation in regions

So how did these clusters start?

It all started with basic science

- Curiosity driven research on fruit flies and worms led to DNA and the Genome Revolution
- The Genome Revolution transformed drug discovery from "hit or miss" to discovery based on understanding of mechanisms
- New tools developed in basic research programs become "platform technologies" for new biotech companies

Government support of research was and is key

- U.S. National Institutes of Health fund discovery science at universities, research hospitals, : \$27.3 billion in FY 2005
- NIH funding also trains the new researchers (graduate students, postdocs, etc.) who will lead the biotech companies of the future
- Intellectual property arising from discovery research forms IP dowry of new companies

And enabling legislation on intellectual property

Federal Law - The 1980 Bayh-Dole Act

- Gave universities title to their patents from federally funded research
- Allowed universities to grant licenses, including exclusive licenses
- Allowed universities to take royalties (and legislated sharing of royalties with inventors.)

Why Bayh-Dole Law was Needed

- University technology is embryonic—neither its feasibility nor market is known
- Development will require <u>high risk</u> investment by company or investor
- Exclusive license to patents required to provide an incentive to make high risk investment—to motivate the "first mover" by protecting against later competitors

Government's Purpose in Bayh Dole

Seeking concrete benefits from Federally funded research:

- Private investment to develop new technology
- New products (and particularly new cures)
- Jobs
- Economic development

Thus developed a different type of supply chain for biotechnology

- Funding from NIH
- · Research at Universities leading to IP
- Formation of new Biotech Company
 - Develop the core technology
 - Identify potential products
- Strategic alliance with Big Pharma Company
 - \$ for Product Development
 - Fund Clinical Trials
 - Marketing and Distribution

The Role of the Research Institutions in Building a Cluster

- Science (where it all starts)
- Intellectual Property
- People
 - Founders
 - Advisers
 - Employees
- Attractive Living Environment

Why did a Biotech Cluster arise in Massachusetts?

- World-class universities and research hospitals (M.I.T., Whitehead, Harvard, Massachusetts General Hospital, Brigham & Women's Hospital, Beth Israel Hospital, Boston University, etc., etc.)
- \$2.2 billion in NIH research grants, FY 2005
- Experienced venture capitalists (originally from other fields), corporate attorneys, other support for startup companies

"Massachusetts is *importing*Company Founders as a result of [its universities]"

- Highly selective universities select "the best and the brightest" students from around the world.
- A large fraction of students who come to Massachusetts for university study or medical residencies stay there after graduation

1997 BankBoston Study

How MIT contributed to formation of the Biotechnology Cluster

A continuing transfer of technology from MIT to industry

- Publications
- The graduating student
- The consulting professor
- The entrepreneurial students and professors
- Collaborative research with industry
- Out-licensing of technology
- Spin-off companies

Attracting the best and the brightest—who then stay and build the community

• "While only 9 % of MIT undergraduates are from Massachusetts, more than 42 % of the software, biotech and electronic companies founded by MIT graduates are located in the state [a total of 1000 companies]this represents 5% of the employment and 10% of the economic base of Massachusetts"

1997 BankBoston Study

Interaction with industry is an inherent part of the culture at MIT

- Founding mission statement of MIT (1861)
 - "aiding generally the advancement, development and practical application in connection with arts, agriculture, manufactures and commerce"

- Long history of consulting and interaction with industry
- Spin-offs were happening 40-50 years ago (e.g. Digital Equipment Corporation, Bose Corporation, etc. etc.)
- MIT faculty were co-founders of some of the earliest biotech companies (e.g. Genzyme, Repligen, Biogen, Amgen)

- In the late 1980's through the 1990's, as spin-off activity increased at MIT, there grew a greatly increased interest in such activities by both the faculty and the students
- Many students chose to enroll at MIT because of the entrepreneurship opportunities

The Entrepreneurial Ecosystem at MIT

- A plethora of people and organizations that support entrepreneurship at all levels of the institution
- A creative blending of MIT with the surrounding business and investment community

Components of the Entrepreneurial Ecosystem at MIT

A. The Students

- Pre-selection for "leadership" in addition to academic skill
- Solid technical education at the state of the art
- Encouragement for faculty and students alike make it easy to start a company
- Encourage risk taking: "Failure is a learning opportunity, not a black mark."

B. The "official" activities encouraging entrepreneurship

- Technology Licensing Office (IP/Licensing)
- Entrepreneurship Center (MBA internships)
- MBA "Entrepreneurship track"
- Deshpande Center (competitive grants for laterstage research plus matching projects with volunteer advisers from the venture capital and business community)

C. Student Clubs

- The "50K" student business plan contest
 - Students raise \$50,000 each year for prizes
 - Judges from the business community
 - Over 100 entries/year
 - Usually 4-8 get venture investment
- Venture clubs in schools of Business,
 Engineering and Science

- D. Activities of Volunteers from the business community—a key part of the eco-system
 - Enterprise Forum (community education, case studies, networking) Over 25 yrs. old!
 - Over 20 chapters, 3 foreign countries
 - Venture Mentoring Service
 - Alumni and other volunteer senior business people from the community mentor new MITassociated businesses
 - Volunteer instructors in short courses (business plan writing, strategy, etc.)

 And literally hundreds of formal and informal seminars and networking activities per year which mix the students, faculty, administration and the business and investment community

We get to know each other on a continuing basis

How are all these activities at MIT connected together?

- NOT centralized
 - New activities arise "entrepreneurially"
 - Complement rather than compete with each other
- It works because the overall mission is clear
 - and the people involved make it work
 - Emphasis on collaborative spirit
 - Value for all sides (university, inventors, business community)

The importance of role models

- Students are continuously exposed to entrepreneurial role models
 - Faculty
 - Fellow students
 - Alumns
 - Members of the business community
- This changes aspirations for future career
- ("I could do it too")

Encouragement to take risks

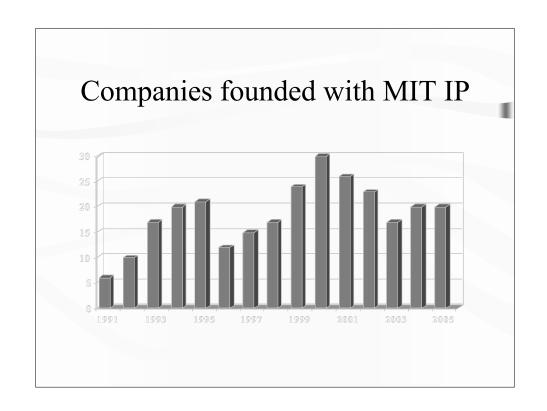
- "Give it a try"
 - We're an experimental place
- Career advice: Take the risk; if it doesn't work, you're good enough to find something else
- Role models: Successful entrepreneurs often discuss for the audience "the first two companies that failed"
- "Failure is a learning experience"
 - Investment community values the experience

FY 2005 MIT Technology Licensing Statistics

- 512 Inventions Disclosed to MIT
- 133 Patents Issued
- 102 Licenses
- 20 Companies founded using MIT IP

MIT's Licensing Goals

- Enhancement of the education process
- Maximize research benefits to society
- Facilitate commercialization of IP
- Creation of companies and jobs
- Provide a fair return to MIT on licensed IP



Spinouts from the MIT Technology Licensing Office

- Of 100 Technology Licenses/year, 20- 30% are to companies formed around the technology ("spinouts")
- Spinout Process is a combination of formal and informal activities in the Technology Licensing Office—aided by an entire "entrepreneurial ecosystem" that pervades MIT

MIT Licensing Philosophy & Terms as they affect Spinouts

- Consider spinout companies favorably
- Usually granted Exclusive License
- Diligence (Development) Terms
- Royalties % of Product Sales
- Annual License Fees
- Patent Costs
- Equity in partial lieu of Fees and Royalties

TLO Startup Activities

Stage 1:

Assess suitability of technology for startups:

- Ambition of inventors
- Breadth of technology
- Strength of intellectual property
- Discuss shape of business
- Introduce founder/inventors to people who can provide strategy help
- Introduce company to potential investors

Stage 2:

Negotiate License Agreement, setting forth:

Intellectual Property estate

Financial terms

Milestones which must be met

Stage 3:

Let Go! Let market forces take over—while monitoring progress

MIT Does Not Provide:

- Money
- Space/Laboratories
- Prototype Development
- Management
- Business Plan Writing
- Formal Guidance (No Board Seats)

Keeping the wall between the university and the company

- Despite (because of) the large number of spinouts, MIT has unusually strict conflict of interest rules.
- Objective is to preserve long-term mission of the university and reputation as disinterested party
- Our philosophy: A few firm rules, separating the university from the company
- No exceptions, no loopholes--but creative crafting of arrangements within the rules

Key components of MIT conflictof-interest rules for startups

- Formal incubation of the company must be outside the university
- We will not do research for the company if faculty member owns equity
- No MIT investment \$ in the company (Equity as a form of royalty is allowed)
- No MIT board seat
- No "special relationship" with MIT once the license is completed

Results/conclusions

- Spinoffs work: Over 300 companies spun out of MIT TLO in 15 years--most in Massachusetts
- Dozens have gone public
- Conflict rules separating the university from the company appear to help rather than hinder company development

What it takes to build companies from university technology

- Govt. support for new technology research
- Clear cut legislation to allow transfer of technology
- An efficient tech transfer process with clear policies—and smart people
- Role Models for founders
- Experienced Entrepreneurs
- Networking Organizations
- Clear University Policy and Conflict Rules

And Entrepreneurial Clusters Will Feed Themselves ("A Virtuous Cycle")

When an Entrepreneurial Cluster forms:

- "Role Models" encourage formation of yet more companies
- Founders of new companies emerge from "more mature" companies
- Employees for new companies have gained experience in former companies
 - Filling the management talent gap that limits entrepreneurial activity in many regions
- Venture capital investors move into town

Cluster Formation needs *Knowledgeable* Local Money

- The new Angels: Successful high tech entrepreneurs now investing in new companies—with knowledge of the industry
- Experienced venture capitalists with knowledge of the technology and the startup process

Knowledgeable Money brings: strategy, guidance, access to managers, connections for alliances, access to additional capital—and patience.

It Takes a Community to Build Companies

- Innovative interactions between academics and the business community
- Continuous close interaction between the the university tech transfer operation and local investors, entrepreneurs, consultants, government, lawyers, etc., etc.

"Tech Transfer is a Personal Contact Sport"

