Institutional Policies
to
Promote Technology Transfer:

Best Practices

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VENTURE CENTER

With thanks to:

Agenda

- Introduction and Setting the Context of the Workshop
- IP and Tech Transfer: Policies and Institutional Processes
  - Tea / coffee
- Entrepreneurship and spinouts: Policies and Institutional Processes

You need three things

- The right policies
  - Relatively easy
  - Plenty of sources
- The right people
  - Harder to find in a new ecosystem
- The right culture
  - Takes time to create

Program

- Needed Policies
  - Ownership
  - IP Policy
  - Conflict of Interest Policy
  - Consulting Policy
  - Equity Policy
- Cultural Issues

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

Why Are Universities Engines of Innovation?

- Faculty are inherently entrepreneurial
  - Have to “sell” their research programs to funding agencies
  - Have to “sell” their courses to students
  - Can “have their cake and eat it too” via “day per week” consulting rules
- 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
- Universities can’t develop their technologies and have to license
  - Funding runs out the closer things get to the market
  - Not their mission
  - Tend to make paradigm-changing discoveries

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

What Is Going to Drive Technology Transfer In Your Institution?

- Why do you want to doi technology transfer?
  - To make money?
  - To indulge faculty?
  - To disseminate the results of your institution's research?
  - To benefit society?
  - To develop the local economy?
- 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*
- Can you do them all?
  - Or are there trade-offs?

Operating Models for Technology Transfer

- Faculty Service
  - Support the creative and entrepreneurial aspirations of faculty and graduate students
- 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

Ownership

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

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
- In late 1970's, dissatisfaction with the model and the results
  - Resulted in the Bayh-Dole Act
    - 1980

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

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

Ownership of IP

- US and UK moved to institutional ownership from government ownership in 1980's
  - Bayh-Dole in 1980
  - UK abolition of NRDC monopoly in 1988

The Spread of the US Model

- Institutional ownership model of academic IP ownership has become dominant
- 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

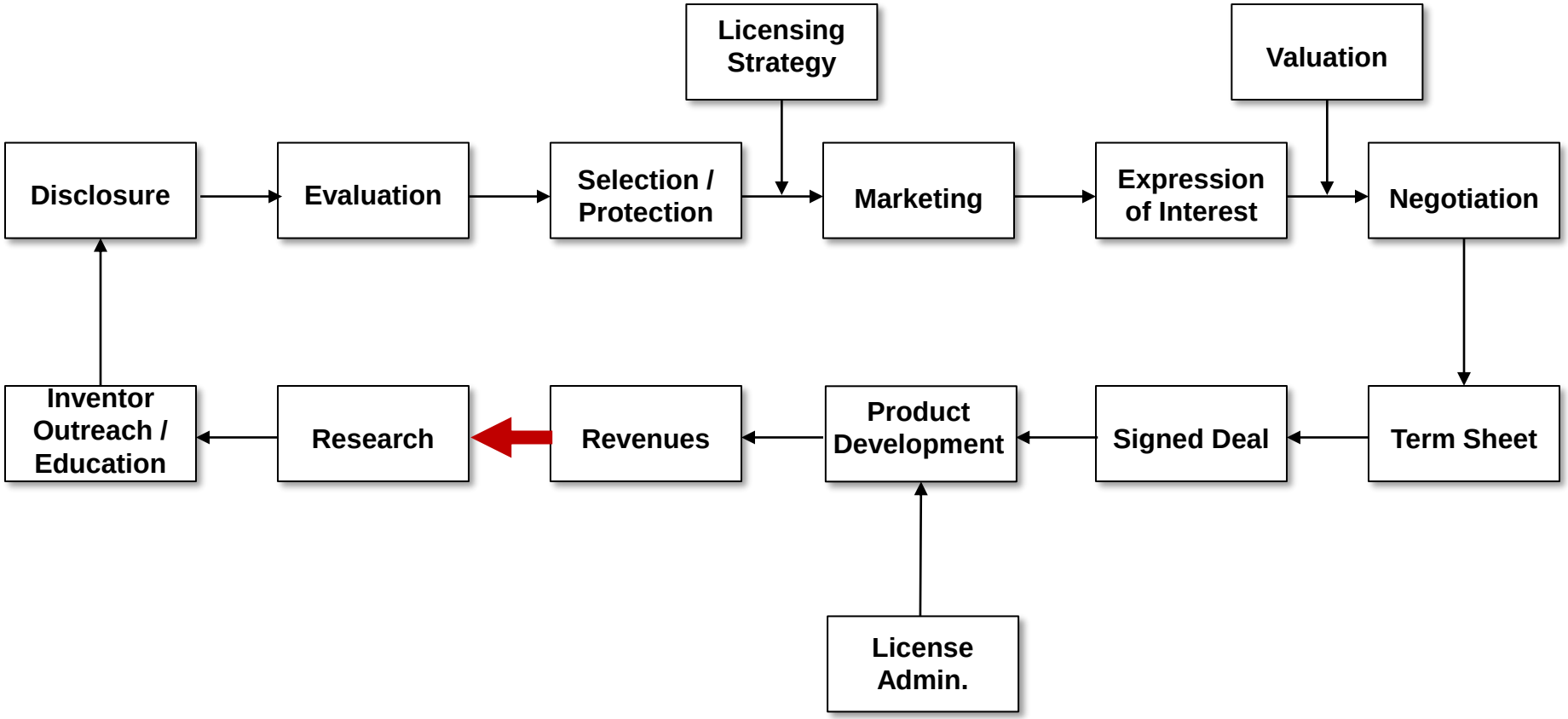
Benefits of Institutional Ownership

- Establish clear title to IP generated by the institution's faculty
- Essential for collaborative research with industry
  - Many international funding arrangements will require it too
- Allows institution to create an IP management office
  - Develop expertise
  - Apply consistent policies and valuations
  - Provide funds for patenting

Ownership Issues

- Most institutions have exemptions
  - Students (except if supported on grants)
  - No significant use of institution's funds, resources, facilities and personnel
- Retain right to practice IP licensed to others
- "Shop right" to IP owned by faculty and brought to the institution

The Technology Transfer Process and Cycle



IP Policy

IP Policy

Example:

DNDi
Drugs for Neglected Diseases *initiative*

The mission of DNDi is to develop safe, effective and affordable new treatments for patients suffering from neglected diseases, and to ensure equitable access to these.

Objectives of IP Policy

- Provide for the intellectual property generated at the institution;
- Promote the progress of science and technology;
- Ensure that discoveries, inventions and creations generated by staff and students are utilized in ways most likely to benefit the public.

Benefits of IP Commercialization

- Foster continuing public support for basic research by showing its public benefit (namely, new products)
- Stimulate more industrial support for research
- Foster community support by creating jobs and new companies
- Help students learn entrepreneurial attitudes
- Enable faculty to see the practical results of research
- Generate new ideas for research themes

Source: MIT IP Policy

Items to be Addressed

- Coverage of intellectual property policy;
- Ownership of intellectual property;
- Disclosure of intellectual property;
- Marketing, commercialization and licensing of patents;
- Distribution of income;
- Rights and obligations of the inventors and the institution;
- Other pertinent issues.

Types of IP Generated by Academic Institutions

- Patents
- Utility models
- Industrial designs
- Copyright
- Literary works
  - Courseware
  - Computer software
  - Video
  - Multimedia
- Geographical indications
- Trade and service marks
- New plant varieties
- Trade secrets
  - Rare
    - Biological materials most common implementation

What's In It For a Scientist?

- It's highly satisfying to see science have an impact beyond academia
  - Giving back to society
- It can bring additional resources into the 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, (s)he may just get really, really rich (I said "may", not "will"!)

Distribution of Income

- Policy should specify who shares in any income generated
- Bayh-Dole Act specifies
  - Inventors must share
  - Balance must be used for education and research
- Standard policy in U.S.
  - Inventors 1/3rd
  - Institution to support research 1/3rd
  - Support TTO 1/3rd
- Ideal policy(IMHO):
  - Inventors personally 25%
  - Inventors' laboratory 25%
  - Institution to support research% 25%
  - Support TTO 25%

Case Study – Drs. Katalin Karikó and Drew Weissman

- U. of Pennsylvania
- Invented uridine ➜ pseudo-uridine substitution
  - Made mRNA COVID vaccines possible
- 2023 Nobel Prize for Physiology or Medicine
- Penn patented the work
  - 2022 Royalty income $1.3 billion
  - Inventors receive 30% personally plus 12.5% for their research account!

Oversight

- Will there be an IP Policy committee?
  - Amend and improve the IP policy
- Will there be an IP Management Committee?
  - Oversee the IP office
- How will disputes be resolved?
  - Initial fact finding and decision
  - Appeal
  - Final authority

Other Topics to Be Covered

- Procedures for public disclosure of intellectual property
- Protocols and restrictions regarding the marketing, commercialization, and licensing of intellectual property
- The rights and obligations of inventors and the institution
- Social issues
  - Global health/affordable access

Developing and Implementing an IP Policy

- Must include all constituencies in the institution
- Look at other institutions
  - All put their policy on the web
    - http://web.mit.edu/policies/13/13.1.html
    - https://otl.stanford.edu/researchers/intellectual-property-basics/stanford-policies-intellectual-property
  - WIPO has a template
    - https://www.wipo.int/technology-transfer/en/ip-po
  - Three components
    - Template policy
      - Very comprehensive
      - 21 choices / alternatives
    - Check list
    - User manual

Consulting Policy

Consulting

- Faculty consulting is critical to the technology transfer process
  - Academic inventions are embryonic
  - Continued faculty involvement is essential
  - They have the know-how in their heads

The Consulting Debate

- The culture of academic involvement in commercialization started early
  - Fight in the MIT Chemistry Department
    - 1920's
  - Chemical engineers said: "Our students will earn their living in industry, so we should study industry's problems to prepare them."
  - Chemists said: "We should study the purest chemistry and then they'll be able to solve any problem."
- Resolution:
  - Professors can spend one day per week consulting for industry
    - If they want to
    - Keep all the money

The Consulting Debate

- This policy has spread across North America
  - Widespread in Europe, Australia
- Allows professors to be seen working with industry without violating Conflict of Commitment policies

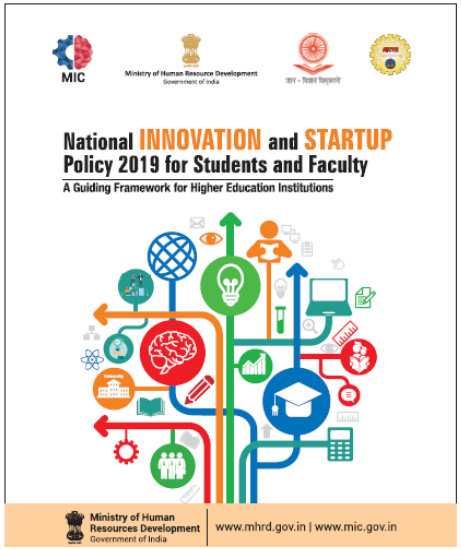
Rules

- Can't use the institution's facilities
  - That needs an SRA
- Can't use students
- Can't give away IP owned by the institution
- Can invent new things at the company's facilities
  - Can own them
  - Can assign IP to the company

Consulting

- Critical to company spin-out process
  - Professor commits his one day per week exclusively to the company
    - Gets substantial equity stake in company
    - In return for the “know-how” in his head
  - Chairs the Scientific Advisory Board
  - Helps guide the company’s technology development programs
  - Grad student/Postdoc joins the company fulltime

India

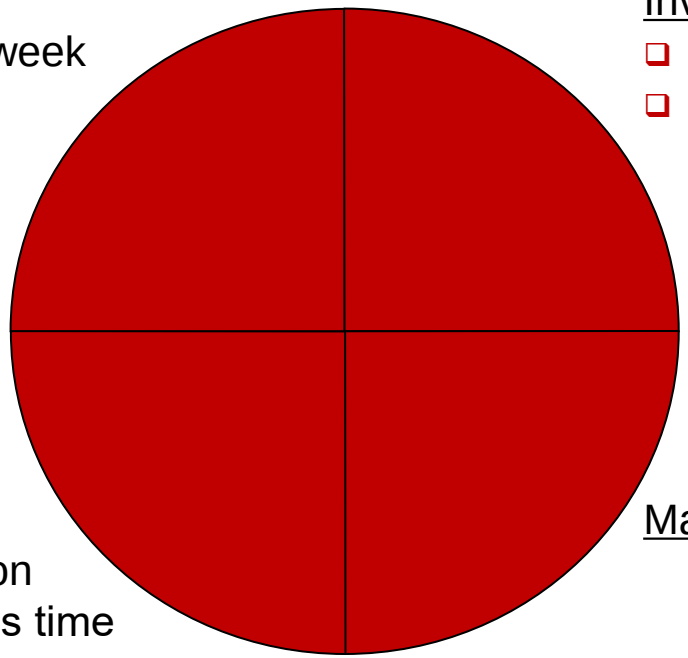


- National Innovation and Start-up Policy
  - Department of Education
  - 2019
- Start-up founder faculty member can:
  - Give institution 2.0-9.5% equity share in start-up
  - Reduce hours worked 20%
- Great concept
  - Too generous to faculty (IMHO)
    - Always demand 9.5%
- My model was a 25% share to the institution
  - At first round funding

Equity – Dividing up the Pie

Inventor – 25%
- Gets to spend 1 day per week

Investors – 25%
- For $50,000 investment
- Values company at $200,000

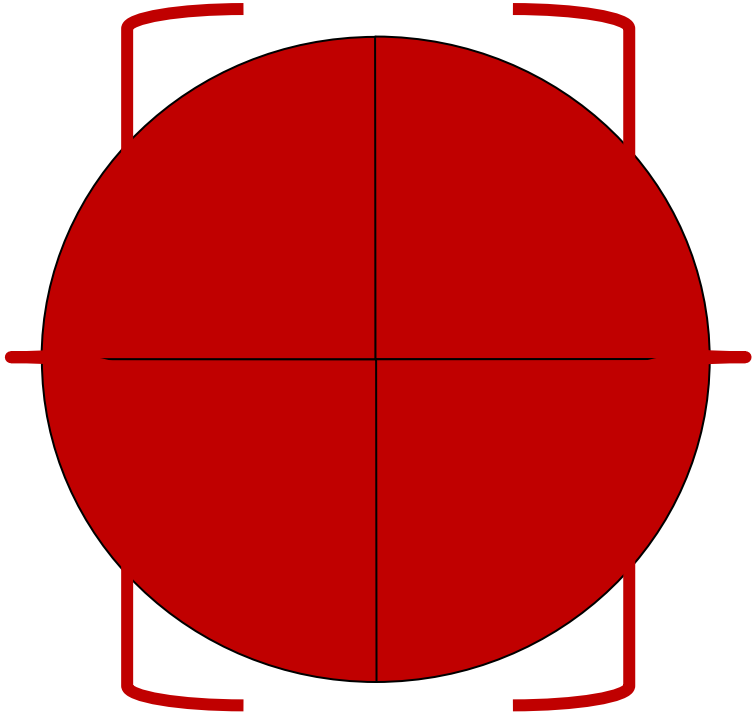


University – 25%
- Part of license consideration
- Compensate for professor's time
- Provide office for 1 year

Management Team – 25%

Equity – Dividing up the Pie

50% to the private sector



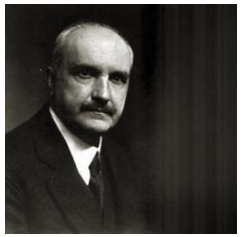
50% to the university

Conflict of Interest Policy

The Impact of Innovation on Academic Institutions

- Commercialization of academic innovation involves new relationships, concepts, pressures and temptations
- All must be anticipated and addressed before heading down the pathway
  - Hard to deal with on the fly
- Years of experience developing things the hard way in the US
  - Learn from them!

"Those who cannot remember the past are condemned to repeat it"



George Santayana

Conflict of Interest

- A conflict of interest doesn't mean a professor has done anything wrong
  - Probably means they're doing things right
- The Yang to the Ying of technology transfer:
  - We encourage faculty to commercialize their research and create relationships with companies
  - Then we bury them in paperwork
  - Will impact their ability to participate in the clinical development of their work
  - May impact their ability to receive corporate support of your work
- Some parts of the institution may resent the commercialization activities

"No conflict

--

no interest"

David Blake, JHU, 1992

BU Policies on Investigators' COI

- It's all about the PSD
  - Project Specific Disclosure
  - Identifies potential conflicts affecting institutional research projects
    - Do they have a Significant Financial Interest (SFI)
- All BU and BMC Investigators must file Project Specific Disclosures.
- Filed when:
  - Funding application submitted to Research Administration
  - IRB application
    - Only if unfunded
  - Any unfunded research project affected by SFI
    - E.g., Working on something for their start-up in their lab
  - Material change not previously disclosed

What Constitutes an SFI?

- You expect to earn consulting income/salary from a company interested in the research in excess of $10,000 in the past or coming twelve months
  - Proposed NIH rule changes will reduce this:
    - $5,000 for publicly traded companies
    - $0 for privately held companies
    - All SFI's to be posted on a public website
- You have any equity in a company interested in the research
  - An SBIR or STTR grant will automatically trigger a COI disclosure
- You have rights in intellectual property used or studied in the research
  - University base salary and financial interests in mutual funds are not SFI

The Culture of Academia

University Leadership in Commercialization

Massachusetts universities have had a long time involvement in research-driven economic development

- Karl Compton, President of MIT proposed using academic technologies to create new industries to lead Massachusetts out of the Great Depression
- Later partnered with General Georges Doriot, HBS, to found American Research and Development Corporation
  - First organized VC fund
    - 1947

A Voluntary Process for Faculty

- 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

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

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

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

The Traditional Scientific Paradigm

The academic dissemination route

The commercial dissemination route

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

Lessons Learned

- Academia can participate in commercialization without compromising the academic mission
- A voluntary process
- Institutional culture is important
  - At MIT, starting a company is **expected** these days

Tea / CoffeeQuestions?

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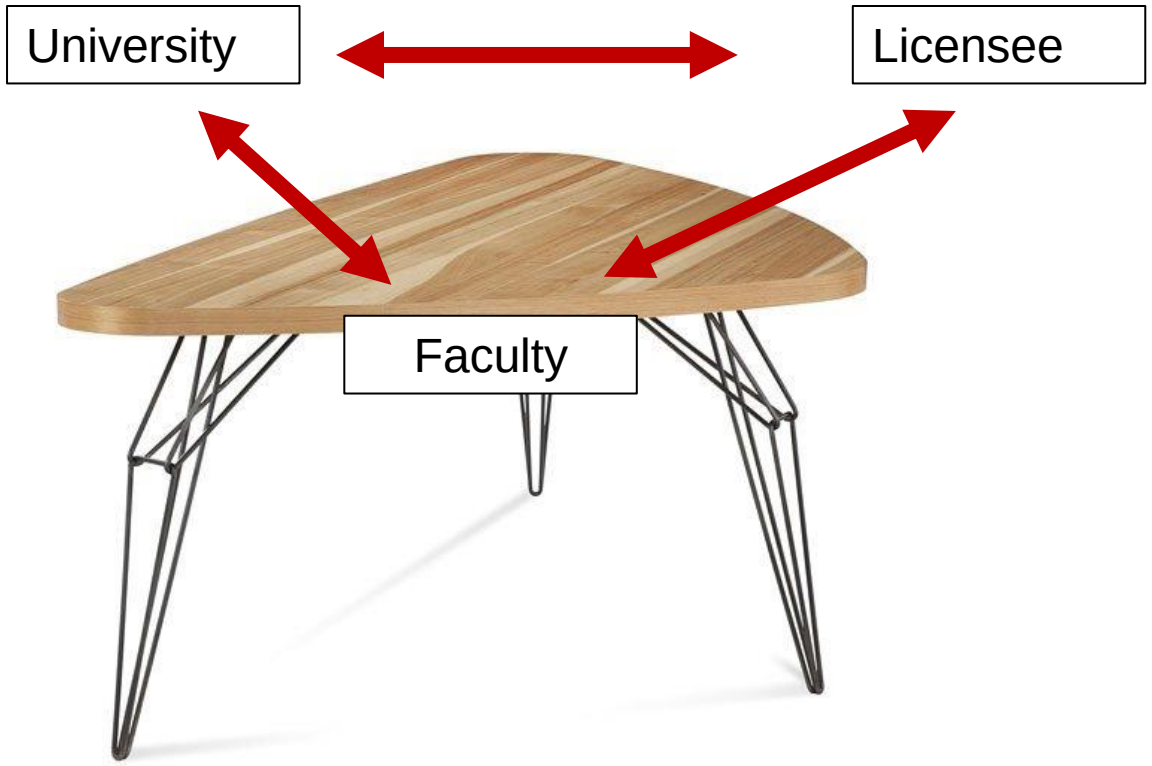
Start-ups, Equity, Entrepreneurship

Start-ups

- Start-ups are different
  - Independent role for inventor even under an institutional ownership IP policy
  - Potential for great wealth
    - Google
      - Stanford made $355 million
      - Two drop out Ph.D. students made $20 billion each!
  - May trigger conflict of interest issues
    - Very strictest CoI policies (Harvard, MIT, U. CA) preclude faculty from receiving research support from start-up if they own stock directly

Negotiating a Start-up Is Different

- Faculty's independent role means the negotiating table has 3 sides



What is the University's Deal with the Start-up?

- In U.S., start-ups are normally initiated by faculty and / or an entrepreneur
- In U.S., university negotiates license to IP with the start-up, just like any normal licensee
  - Normal milestones, AMR's, running royalties, sublicense income sharing, etc.
  - Receives stock in start-up in lieu of Upfront Fee
    - Company should not be asked to pay license fees upfront
      - Not much money at this stage
      - Should all go into developing the technology
    - Some U.S. universities even spread patent cost reimbursement over multiple years

What is the University's Deal with the Start-up?

- How much?
  - Two models
    - Co-Founder
      - University gets same number of shares as the other founders
        - E..g., 4 Founders at 25% each ➔ 5 Founders at 20% each
    - Anti-dilution
      - Give me [5%] now, but keep me at [5%] until [$5 million] has been raised in equity funding
  - Sound very different
    - Actually work out pretty similarly
  - U. of California has a policy of less than 10%

What is the University's Deal with the Start-up?

- In U.S., university usually doesn't invest in the start-up
  - Pre-seed funding via grants
    - Non reimbursable
  - May provide seed funding, if it has a seed fund
  - Some universities may invest in later rounds to preserve ownership
  - Some universities are forming partnerships with VC funds
    - VC fund makes the investment decisions
- Normally, faculty stays at the university
  - Works with start-up using one day per week consulting policy
- Grad students / post-docs working on the project often join the start-up
  - After research done and published, PhD received

Different Models in Europe

- Some bigger U.K. universities are much more aggressive about start-ups
- Initiate and control start-up formation and initial fund raising
  - Finish up with 50% of the founders' round of stock
- In U.K., a number of universities have affiliated venture funds
  - Linked to one university or a group of universities
    - E.g., Oxford has a £850 million fund

Faculty's Role in the Start-up

- Will have an extraordinary interest in the license terms
  - Get their normal share per patent policy
    - But may argue for concessionary terms to maximize equity value
  - Remember the 3-sided table?
- Will have an independent negotiation with the start-up for terms of his / her consulting agreement
  - Chairs Scientific Advisory Board
  - Commits their one day per week consulting time exclusively to the start-up
    - Some defined period of time
  - Gets an annual consulting fee
  - Gets stock in start-up directly
    - In addition to university's stake

An Alternative to Owning Stock

- Stock in a start-up can't be sold until company is sold or gets acquired
  - A "Liquidity Event"
  - Who cares about owning stock they can't sell?
- An alternative is to have an Exit Fee or Change of Control Fee
  - Cash payment when start-up is acquired or goes public
    - Essentially a non-dilutable equity interest
  - E.g., NIH
    - Precluded by law from accepting stock in start-ups
    - Has a schedule of exit fees in their standard license
      - 0.75% of FMV if only *in vitro* data at time of license
      - 1.5% of FMV if animal or toxicology data at time of license
      - 3.0% of FMV if human clinical data at time of license

Distribution Issues with Equity

- When to sell?
  - Most universities have a “sell at first liquidity” policy
    - Often a six month lock-up period after IPO
  - Stock can go up (Google) or down (Facebook) after the IPO
    - Endowment invests in the stock market, not the TTO
    - Liability issues to inventors if stock goes down
  - U. of California allows some stock to be held
    - 50% at first liquidity
    - 50% after 6 months
    - Option to hold upto 25% for upto 5 years
      - If TTO requests
      - Must be elected at time equity is received
  - I always advised my inventore to sell at least a third or half at first opportunity

Distribution Issues with Equity

- When to distribute to inventors?
  - When license signed?
  - Immediately prior to IPO?
- What to distribute?
  - Only stock received for license
  - Not any stock received from investment or incubation
- Whom to distribute to?
  - Do inventors get their Patent Policy share of sale of equity?
    - BU policy was “Not if they got a comparable amount to the university”
    - Stanford policy was “Yes”
      - Larry Page got 1/3rd of Stanford’s $355 million
        - His own stock was worth $20 billion after IPO

Assigning the IP

- U.S. universities don't assign IP
  - Not permitted under Bayh-Dole without permission of funding agency
    - They won't give it
      - If Google can get started with an exclusive license from Stanford, not an assignment……
  - The ecosystem has come to accept this
- Importance is that you can terminate a license by giving notice
  - Non-performance
  - Material breach
- Get IP back and relicense
  - With all the know-how the licensee has developed
- Much weaker negotiating position if you've assigned

Assigning the IP

- In other jurisdictions, the Bayh-Dole legislative shield doesn't exist
  - Pressure to assign
- Try and limit
  - E.g., not till
    - IPO or acquisition by publicly traded company
    - Launch of product
  - By this stage, need to terminate has disappeared

Other Things Universities Do to Support Entrepreneurship

- Entrepreneurship Centers
  - Incubation
    - Can be a regional initiative
      - University spin-outs
      - Other local companies
  - Mentorship
    - Regional initiative
  - Funding sources
    - University
    - City
    - National government

A Few Final Thoughts

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
  - 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

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!

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

Thank you for listening.

Questions?

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