History and Evolution of
University Intellectual Property (IP)-based Transfer of
Technology (TT), and Its Relation to the University Mission:
The USA Experience and the United Kingdom Experience

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45 minutes

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IP, TT and the University Mission: Why do we do it?

Innovation and the Role of the Modern University in the National economy.

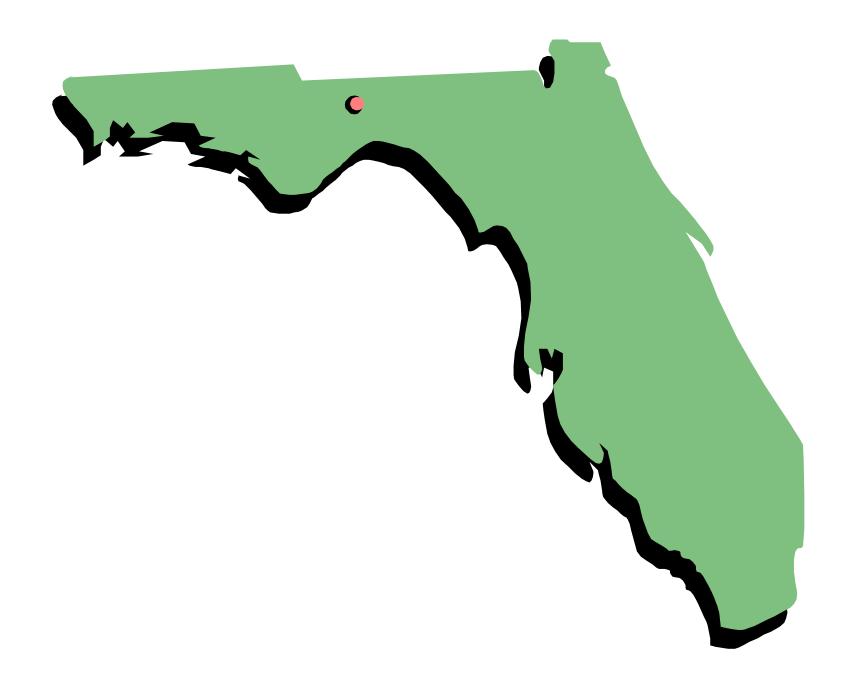
Mission: Assisting the University to meet its own Goals – Setting Expectations.

Enabling the IP Environment – How to Assess, Communicate and Set Expectations of Administration and of Faculty and of other Researchers.

John Fraser

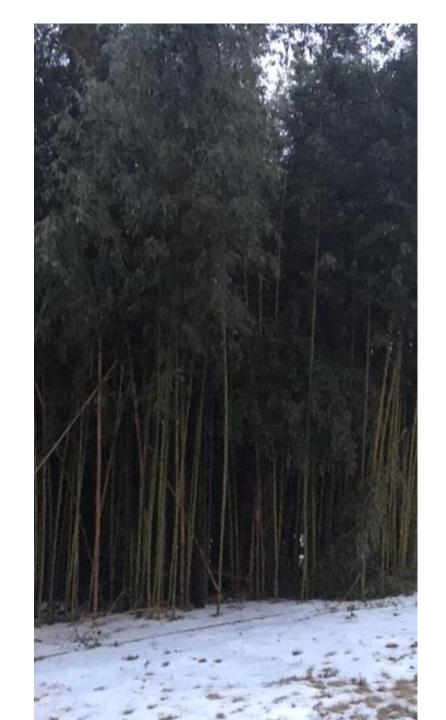
- President of Burnside Development, a technology transfer consulting firm. Clients in Chile, China, Philippines, Serbia, USA.
- President of AUTM in 2006-2007. Visited 20 countries to assist with technology transfer.
- Former Assistant Vice President of Research, Florida State University, Tallahassee, Florida and Executive Director of the Office of Commercialization (2014-1996).











Technology Transfer and the University Mission

University culture derives from its Mission of teaching, research and community service and is based on the free exchange of ideas and providing the public with access to an impartial source of information.

- 1. Teaching educating the next generation;
- 2. Research fundamental investigation of issues both basic and applied;
- 3. Community service e.g. medical clinics; professional schools law, accounting.

Human Institutions

- Except for specific organized religions, universities are the longest-standing human institutions. Dramatic change unlikely:
 - Universities a 'recent' innovation is the creation of a Medical School to train doctors.
- A 4th part of the Mission is slowly emerging –
 Helping to improve the economy and create Jobs.
 - This builds on the activities of education/students;
 research/faculty; service/clinical studies and business
 and law, academic entrepreneurship.

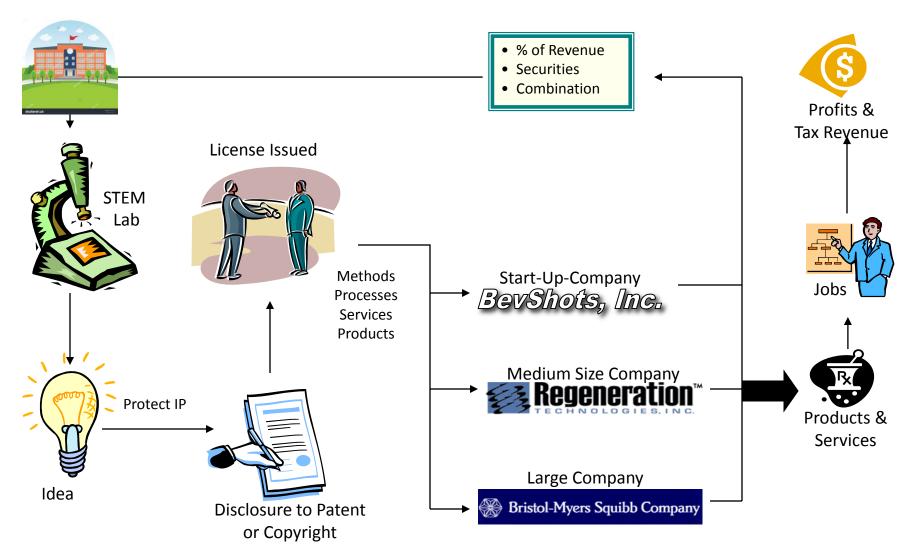
AUTM Video – What is TT

Technology Transfer – 2 Types

TT: the movement of technology and finished products from developed countries to be sold in emerging economies. This can hinder the emergence of local industry. NOT us.

Academic TT: is the movement of knowledge and discoveries from publically funded research organizations via the private sector to the public. Can accelerate the emergence of local industry.

Lab To Market – A Chain of Value

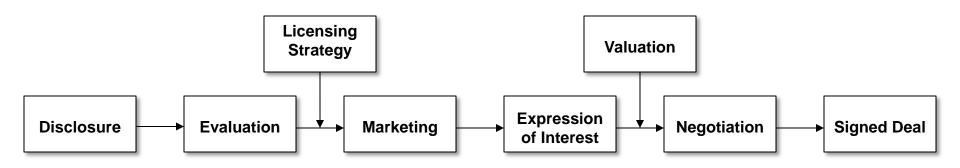


By permission – the Florida Research Consortium 2008

What is TT?

- Traditional academic technology transfer:
 - Disclosure, protect via <u>patent</u>, market, usually an exclusive license to one company.
- The Modern academic technology transfer:
 - Traditional academic technology transfer, PLUS
 - Disclosure, protect via <u>copyright</u>, <u>restricted access</u> to data or biological materials, or software, market, multiple non-exclusive licenses to multiple companies.

The Technology Transfer Process



WHY do Technology Transfer?

- Helps Build Reputation of the University.
- Help address Society's real problems.
- Reduce the image of an isolated Ivory Tower.
- Provide another justification for public monies to support the University and its research base.
- Encouragement from Government: NSTDA.

History of academic technology transfer in the USA

- One of the very first formal technology transfer licenses <u>ever</u> was signed by the University of Toronto, Canada to help commercialize the research results of Banting and Best, the isolation of Insulin and its therapeutic use to treat Diabetes.
- This discovery was considered one of the miracles of modern medicine because of its dramatic, almost magical effects on diabetics.

History of academic technology transfer in the USA - 1

The legal basis for the **U.S. patent system** stems from the 1776 Constitution, Article 1, Section 8, which defines the powers of Congress. It states that, "Congress shall have Power ... To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

History of academic technology transfer in the USA - 2

 The ownership of government funded research results fluctuated back and forth between the Funder (government) and the Performer (companies or universities) until 1980.

 In 1980, the federal Bayh-Dole Act was implemented and provided the certainty of ownership to the Performer by default, but did not provide funding for IP Commercialization.

History of academic technology transfer in the USA - 3

- Until the B-D Act in 1980, only a small group of larger research universities performed formal academic technology transfer with dedicated staff.
- In 2015, over 190 US Universities and Hospitals reported on their TT activities in the AUTM Survey.

There is a lot of Talk about Academic Technology Transfer.

But Does it Work?

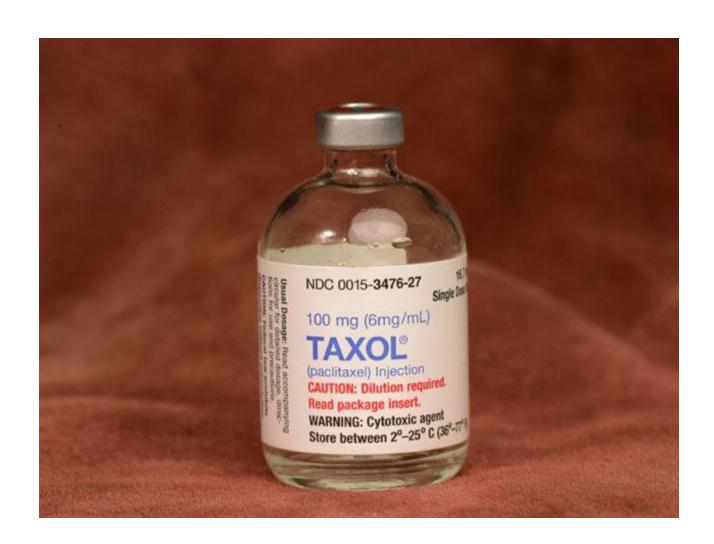
Example # 1: What do these Products have in common?

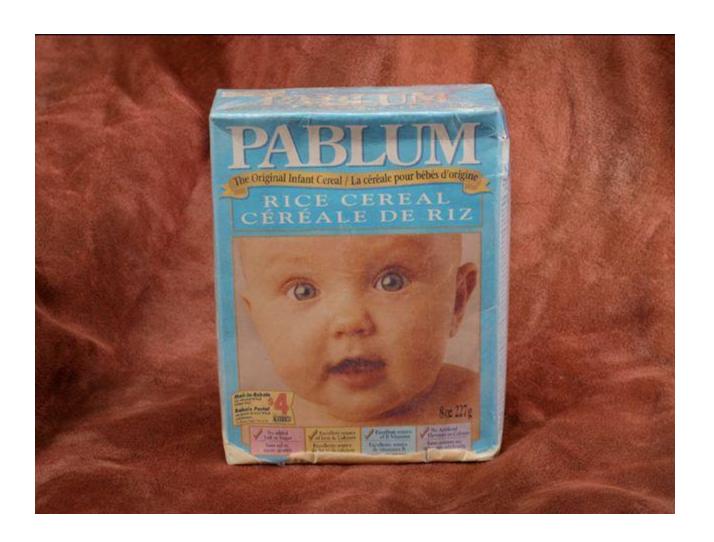














What do these Products have in common?

Want to see 600 more products based on university research?



www.betterworldproject.org/

Example # 2: Where do Drugs Come From?

A study* of Drugs approved by the US FDA over an 18 year period ending in 2011, showed that 20% (190) of the approved innovative drugs (New Molecular Entities) were invented/discovered during federal government sponsored research on US university campuses and at the USA National Institutes of Health.

*NEJM, Stevens et al. Feb. 10, 2011, pg535ff.

Approved Drugs Discovered at Academic Institutions

<u>Drug</u>	<u>Indication</u>	<u>Discoverer</u>	Marketer
Rx			
Abelcet	Systemic fungal infections	M.D. Anderson	The Liposome Company
Adenocard	Cardioprotectant	U. of Virginia	King/Fujisawa
Allegra	Allergies	Georgetown	Aventis
AmBisome	Anti-fungal liposome	U. of California	Fujisawa
Amevive	Psoriasis	U. of Michigan	Biogen
Avicine	Cancer	Ohio State	AVI Biopharma
BeneFIX	Haemophilia B	U. of Washington, Oxford	Wyeth
Botox	Rhinorrhea	Mt. Sinai	Allergan
Bexxar	Non Hodgkins lymphoma	U. of Michigan	Corixa
Calcibind	Hypercalciuria	U. of Texas Southwestern	MedImmune
Carboplatin	Cancer	Michigan State	Bristol-Myers Squib
Cisplatin	Cancer	Michigan State	Bristol-Myers Squib
Cytogam	Cytomegalovirus	U. of Massachusetts	MedImmune
Decapeptyl	Prostate cancer	Tulane	Ipsen
Elmiron	Bladder pain from interstitial cystitis	U. of California	Ortho McNeill
Embrel	Rheumatoid arthritis	MGH	Amgen
Emtriva	AIDS	Emory	Gilead Pharmaceuticals
Epicel	Transplantable skin for burn treatment	Harvard	Genzyme Tissue Repair
Exosurf	Premature birth respiratory distress	U. of California	Glaxo
FluMist	Influenza vaccine	U. of Michigan	MedImmune
Habitrol	Smoking cessation patch	U. of California	Novartis
Hepatitis B Vaccine	Hepatitis	U. of California	Merck
HibTITER	Bacterial meningitis vaccine	U. of Rochester	Wyeth

Approved Drugs Discovered at Academic Institutions

<u>Drug</u>	<u>Indication</u>	<u>Discoverer</u>	<u>Marketer</u>
Rx			
Insulin	Diabetes	U. of California	Eli Lilly
Leukine	Neutropenia	Various	Schering AG
Leustatin	Hairy cell leukemia	Brigham Young/Scripps	J&J
LYMErix	Lyme disease vaccine	Yale	Glaxo
Neupogen	Neutropenia	Sloan Kettering	Amgen
ONTAK	Cutaneous T cell lymphoma	Harvard	Ligand
Panretin	Kaposi's sarcoma	Salk Institute	Ligand
Periostat	Periodontal disease	SUNY	Collagenex
Prozac	Premenstrual dysphoric disorder	MIT	Eli Lilly
Remicade	Rheumatoid arthritis, Crohn's disease	New York U.	J&J/Centocor
Respigam	Respiratory syncytial virus	U. of Massachusetts	MedImmune
Restasis	Dry eye	U. of Georgia	Allergan
RheoPro	Unstable angina	SUNY	J&J/Centocor
Therasphere	Hepatocellular carcinoma	U. of Missouri	MDS Nordion
Thiola	Cystinuria	U. of Texas Southwestern	Mission Pharmacal
Trusopt	Glaucoma	U. of Florida	Merck
Urocit-K	Calcium renal stones	U. of Texas Southwestern	Mission Pharmacal
Visudyne	Macular degeneration	U. of British Columbia/Mass	Novartis
Zerit	AIDS	Yale	Bristol-Myers Squib
Ziagen	AIDS	U. of Minnesota	Glaxo

Approved Drugs Discovered at Academic Institutions

<u>Drug</u>	<u>Indication</u>	<u>Discoverer</u>	<u>Marketer</u>
OTC			
Caltrate Colon Health	Colon cancer prevention	Dartmouth	Wyeth
Citracal	Osteoporosis	U. of Texas Southwestern	Mission Pharmacal
HMB/B-Advantage/Juven	Exercise adjuvant	Iowa State/Vanderbilt	Metabolic Technologies, Inc
Pepcid Complete	Heartburn treatment	Brigham & Women's	J&J Merck Consumer Pharm.
Renova	Skin wrinkles, brownspots	U. of Pennsylvania	J&J
In Vivo Diagnostics			
Cardiolite	Cardiac imaging	Harvard/MIT/U. of Cincinnati	Bristol-Myers Squib
Ceretec	Brain imaging	U. of Missouri	Amersham
Myoview	Myocardial imaging	U. of Cincinnati	Nycomed Amersham
Miraluma	Mamography interpretation	Harvard	Bristol-Myers Squib

Drug Production Technologies

Production Methods	
Recombinant DNA	Stanford/U. of California
Mammalian cell production (Axel)	Columbia
Mammalian cell production (Ringold)	Stanford
Recombinant Antibodies	City of Hope
Taxol	Florida State

Example # 3: Non USA

- India: Eggplant Sathguru (India) a private company and Cornell University (US), added a pest inhibitor and distributed varieties throughout SE Asia.
- Chile: Pontifical University of Chile, Santiago, invented an earthquake damping device widely sold thought the Pacific Rim through a private spin-out company.
- Philippines: University of San Carlos, Cebu City created a process for mango waste - peels and seeds - to be converted into high value products in the form of flour, pectin, antioxidants, polyphenols, briquettes. Scaled up (50T/day) through a spinout company financed by a local entrepreneur who hires former scavengers from the dumps where the waste had gone.

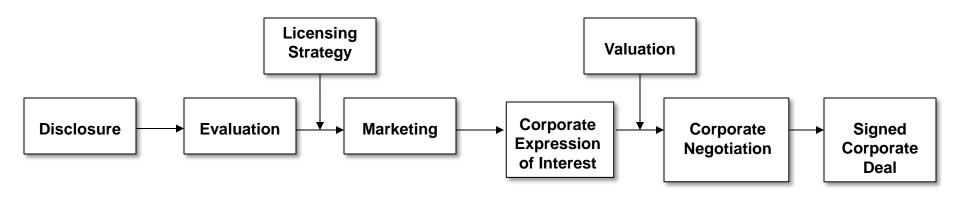
Academic Technology Transfer Does Work, and

It Works outside the US/Canada and the UK.

Increasingly, the University and its Society realize that:

- Exposing students how to work with, and in, the private sector through on-hands projects during their university experience is increasingly important.
- The traditional impact of the University through education and research is no longer enough as the world changes.
- Research collaborations with companies,
 Entrepreneurship and transferring technology can lead to creative problem solving, access to new financial resources and job creation.

The Technology Transfer Process



HOW DO YOU DO TT?

- You need an academic IP Policy. In Thailand, entities that prove they have TT capability are entitled to retain ownership of their own government funded research results.
- You need an IP structure, focus the TTO.
- You need people in the TTO.
- You need a TTO budget.
- You need a responsive Faculty.
- You need Time.
- You need senior University Leadership to be knowledgeable and supportive of the activity as it enhances the University Reputation.
- You need to recognize how Corporations think.

MISSION STATEMENT

- This is a good example of a modern Mission Statement of the technology transfer office / commercialization activity:
- To assist the University to achieve its Goals of education, research and community service, by growing University-Industry relationships particularly in the area of research collaborations in order to bring results of research and creative works to the benefit of Society in the form of new products and services which save lives, improve the quality of life and increase corporate competitiveness and productivity.

ISSUES

- Historical: US patent licensing to existing corps.
- Are we in the twilight of the Golden Era of 'easy to license' life science patents?
- Recognizing value in Software or Apps, Creative Works, Biological and Other materials.
 - Patent licensing: 10-12% of faculty involved;
 - Add another 10% of faculty incl. non STEM faculty;
 - No patent costs up front;
 - Fast to market, but Copyright clearance complex issue.
- Recognizing value in local spinout companies based on Founder's research results.

SETTING EXPECTATIONS

- Stanford University:
 - Total sponsored research budget is \$1 billion *
 - 4,000 grad students, 1,100 faculty undertaking research.
 - Strong medical and engineering schools, as well as solid biology, chemistry and physics disciplines
 - 500 invention disclosures/year equally physical/life sciences

Stanford University

- Over its first 36 years of history, OTL:
 - received 6,400 disclosures
 - took 15 years of OTL operation to <u>breakeven</u>!
 - 80% of disclosed inventions did not bring in <u>any</u> revenue!
 - 3 inventions (Google; Gene Splicing and Functional Antibodies - \$50million⁺ each) generated 67% of cumulative OTL Income
 - 90% of Licensed disclosures covered just the patent expenses!

In 2006, 109 new Stanford licenses signed:

- 62% are non exclusive,
- 25% are exclusive, and
- 13% are options to licenses.

In USA, after 35 years from 1980 Bayh-Dole: 32% of licenses to large corporations, 50% to SME's, and 18% to spinouts.

Do not undertake a technology transfer program for the Revenues!

TIMING

- It may take 12 months to close a deal with a Company, then years to the marketplace.
- Remember Stanford University Metrics.
- Overnight Success: It took Bill Gates and Steve Jobs over 25 years (a whole generation) to grow their companies to significant size.
- A Faculty member's active research career is over 25 years long.
- Commercialization and a successful research career have similar time frames.

SUMMARY

- Academic technology transfer helps fulfil the University Mission.
- Why do it? To enhance the University Reputation.
- There are 2 types of TT
 - commercial B2B and academic TT U2B.
- It Works. Examples from around the World.
- Expectations: Long Timeframe but in keeping with timeframes of the University.

REFERENCES

- The Licensing Journal
 - Lessons learned in 25 years
- Jane Muir video
- Oren Herskovits video on the time from research to market via Licensing at Columbia University
- 2 pages of the U of T Insulin License
- US TT the numbers
- Non US TT examples more details
- Extra PP's on 'What is TT ?'
- NEJM Drugs List

THANK YOU!

Q & A

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