

Basics of Technology Transfer

Welcoming remarks will begin at
11:55 a.m. Eastern Time.

The formal presentation will begin at Noon Eastern

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Basics of Technology Transfer

Speakers:

Dr. Ellen Purpus, *Director, Office of Technology Transfer*
Marc Sedam, *Managing Director of Technology Transfer*

July 31, 2014

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- *AUTM Better World Report*
- AUTM Salary Survey
- AUTM Technology Transfer Practice Manual
- AUTM Licensing Activity Survey (currently for United States and Canada)
- AUTM Update

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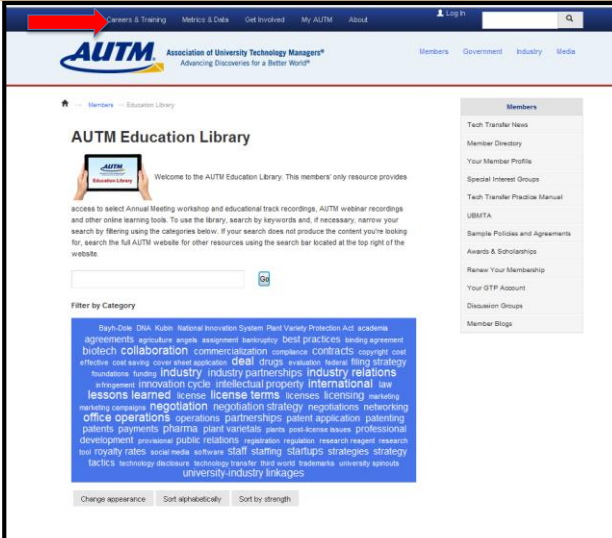
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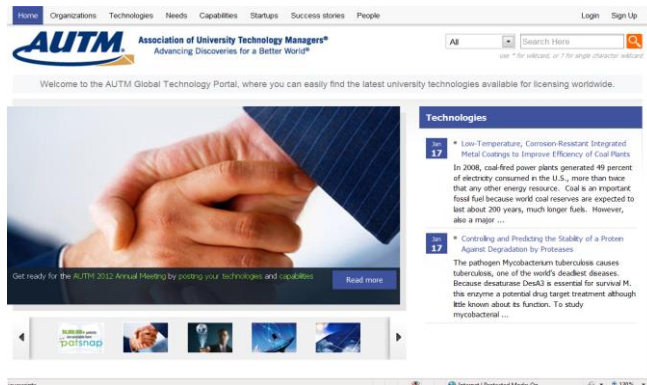
Seeded content:

- 23 Annual Meeting workshop recordings
- 10 relevant links to the TTP Manual
- 5 educational webinar recordings
- Additional content added annually by committee

<http://www.autm.net/source/ed-library/index.cfm>

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Basics of Technology Transfer

AUTM Webinar

31 July 2014



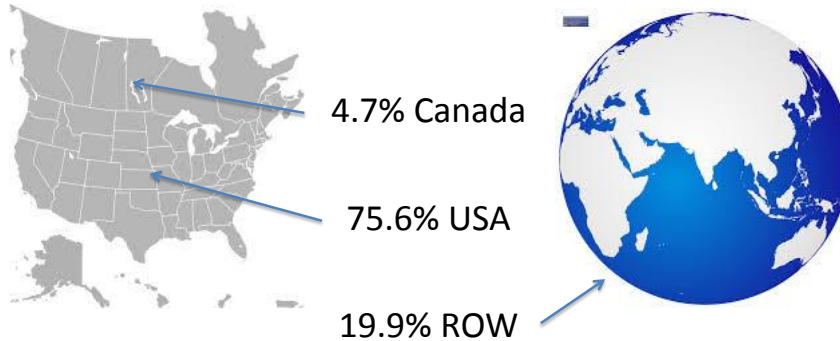
Title here

What is AUTM?

A volunteer organization that brings together over 3200 technology transfer professionals in more than 60 countries ***to support and advance academic technology transfer globally.***

- 65% work in academic settings
- 35% work in industry

Membership Profile



Why Does AUTM Exist?

- To support and to advance academic technology transfer globally
- AUTM members seek to advance research discoveries from academia to the marketplace for societal benefit

Positive Economic Impact

- University licensing increased U.S. gross industry output by \$836 billion between 1996 and 2010
- These technologies support an estimated 3 million jobs in the economy
- Tech transfer helped to create 705 new companies and 591 new products in 2012 alone
- Direct correlation between amount of federal dollars invested in research and the innovations that research creates

How Does AUTM Support Members?

Website

Advocacy

Annual Meeting

Regional Meetings

Metrics and Surveys

Professional Development

Global Technology Portal (GTP)

www.autm.net

- Latest news and events in TT
- Online training and education
- Policy and advocacy suggestions and information
- Library only available to members

Coming soon! Learning management tool to track and suggest educational opportunities.

BASICS OF TECHNOLOGY TRANSFER

aka Technology Commercialization, Technology Development

In the beginning.....



Basic Research



Inventions and Discoveries



Role of the Tech Transfer Office

- Professionals who analyze marketplace, understand the technology's "use case" and patent/licensing issues
- Resources for connecting people and/or companies looking for new technology inventions; helping faculty further develop the technology pipeline

Goal: Maximizing an Invention

- Under Bayh-Dole, university and researcher may retain title to inventions made using federal research dollars
- This system incentivizes the transfer of technology to the private sector for job creation
- Any net licensing revenues to universities go back into more research and/or education, as well as patenting costs
- Other benefit: initial development usually happens locally
 - 2012 AUTM survey found that 78.6% of startups formed that year were in the same state where the research was conducted

Question	Subject Area
What do we know about it	Invention Disclosure
Who funded it?	Compliance
Was IP created?	Triage
Is there a market for it?	Evaluation
Can we find a licensee?	Marketing
What is the value?	Valuation
Does my licensee agree?	Licensing

Nine Points to Consider

http://www.autm.net/source/NinePoints/ninepoints_endorsement.cfm

1. Reserve right to practice inventions
2. Encourage use of idea
3. Minimize licensing improvements
4. Manage conflicts of interest
5. Ensure broad access to research materials
6. Carefully consider enforcement
7. Understand export regulations
8. Be mindful of working with patent aggregators
9. Consider “carve outs” for unmet needs

Invention Disclosure

- Starting point for most TT discussions
- Summary of what the inventor *thinks* you need or want to know
- Should summarize the invention, who funded it, and possible commercial outcomes

Helpful Hint: Disclosures

- Verify that the invention disclosure is complete, comprehensive, and accurate
 - Ask questions early to avoid problems later

Compliance

- Keep your funders happy by telling them what you've done
- Federal reporting is critically important
 - Shows impact of funding
- Federal agencies want to know impact of their funding on the lives of US citizens

Helpful Hints: Compliance

- Keep current! Few people enjoy filling out forms. Fewer still enjoy an audit from the Federal government.
- iEdison is not the only compliance route. Make sure you know how to report for each agency.

Triage

- Determine whether the opportunity has high or low potential quickly and allocate resources accordingly
- Objective is “go/no go” to the next stage of interest

Triage: Points of Emphasis

- Evaluation of Disclosure
 - Sponsor commitments
 - Patentability assessment
 - Publication/Disclosure of information
 - Commercial potential
- Strategy Considerations
 - Exclusive/non-exclusive licensing
 - Field of use licensing
 - Financial considerations
 - Additional sponsored research funding
- Marketing



Market Evaluation and Marketing

- First determine who wants your product (evaluation), then how you reach them (marketing)
- Market specifics will help dictate license structure and strategy as well as fee/royalty structure

Helpful Hint: Triage

Inventors can be the biggest help with triage.
Just because they disclosed the idea doesn't
mean they think it's awesome. Ask questions.

Valuation

- Valuation is the art of licensing
- There is only one wrong way to value a licensing opportunity and that's not to try
- Get to know spreadsheets

Valuation Basics

- Research gives you comparables
 - 10-K files give actual numbers
 - AUTM's new TransACT database will help with info from your peers
- Learn how to run a spreadsheet
 - Understand concepts of risk, time value of money, and discounted cash flows
- Share your assumptions with the partner

Valuation: Helpful Hint

- Objective of valuation is NOT to determine the price of the opportunity but to create a framework from which you can negotiate based on your assumptions
 - And your assumptions are always wrong

Licensing

- Offers use of technology (often) without ownership of the asset
- Before offering a license try to understand what the partner *needs* versus what they *want*
 - Needs are permanent. Wants can be temporal
- Synchronize your licensing structure against the valuation model

License Negotiation

- University negotiates deal on behalf of all stakeholders
 - Faculty
 - University
 - Government
- Financial and non-financial drivers

Licensing: Doing the Deal

- Many ways to commercialize a given technology
 - Option
 - Non-exclusive License
 - Exclusive License
 - Field of Use (FOU) License
 - Tangible Property License
 - Create a new organization
- Or publish, and extract no financial value

Licensing “Levers”

- Upfront consideration: Cost to get in the door
- Royalty rate: Financial representation of risk
- Milestone payments: You get paid, we get paid
- Diligence: Ensures commercialization path

Diligence: Helpful Hint

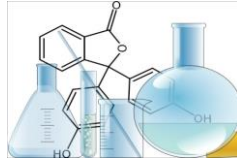
- Start diligence requirements from the perspective of the licensee. Ask what *they* think the commercial path is.
 - Gives data points to update valuation model
 - If you agree, the discussion is over
- First seek to understand, then to be understood

We've only scratched the surface of these areas. Look what else you have to do...

Building a Technology Ecosystem



Patents/licensing agreements



Proof of concept programs



Industry partnerships



Business models



Innovation/Entrepreneurship
Initiatives



Venture capital/
patenting costs

Why is IP Important?

- Induce Development
- ... for the public good
- ... encouraged by the US government
- ... economic benefits
- Attract Industrial Research Sponsorship
- Faculty has the satisfaction of knowing that their work has been utilized to help people
- Faculty shares in the revenues

TYPES OF INTELLECTUAL PROPERTY

- Patents protect ideas.
 - must file a patent application
 - Copyrights protect expression.
 - must create the form of expression
 - Trademarks protect designation of source of goods.
 - must use the trademark
 - Trade secrets are trade secrets.
- *Intellectual property strategies often involve a combination of patents, copyrights, trademarks and trade secrets.*

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Types of Patents

- **Utility** - For any “new and useful process, machine, article of manufacture, or composition of matter, or any new and useful improvement thereof.”
- **Plant** - For any “distinct and new variety” of asexually reproduced plant.
- **Design** - “new and original design” for metal, for fabric, for statues, for marble, and for the shapes of these objects, or for the patterns or pictures affixed to them.

Patents only give the owner the right to exclude others from practicing the invention.

Types of Patent Applications

- Provisional - not examined; a “placeholder”
- Non-prov. - examined and issues as patent
- Divisional - contains claims to “restricted” inventions; same specification as parent
- Continuation - same specification, different claims than were presented before
- Continuation-in-part - contains some new material (rarely advisable)
- Reissues and reexaminations

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Parts Of The Application

- Title Page: Names the Applicant and Inventor(s)
- Background
- Summary of the Invention
- Brief Description of Drawings / Drawings
- Detailed Description
- Claims
- Abstract

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The Application Process

- Preparing the Application
- Filing the Application & Formal Documents
- Restriction Requirement – divides applications into more than one invention.
- Office Action(s) – Usually three
- Response(s)
- Advisory Action - Possibly
- Allowance
- Issuance and Continuing Applications
- Appeal - If application rejected

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Invention

Two elements to any invention:

- **Conception** - an idea that is complete enough that the invention can be reproduced by others; the “light bulb” paradigm
- **Reduction to practice** - when the invention has in fact been made/practiced; reduction to practice may be actual or constructive

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Inventorship

“The threshold question in determining inventorship is who conceived the invention. Unless a person contributes to the conception of the invention, he is not an inventor ... [and] reduction to practice, *per se*, is irrelevant”

However, while conception may be the key, reduction to practice may be very instructive.

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Assessing Inventorship: Inventorship ≠ Authorship

- First determine what the invention is; focus on the claims and what is patentable, and then examine both conception and reduction to practice (*i.e.*, was conception complete?)
- Who did what, under who’s instruction, and at what time? Must ask all putative inventors.
- Correction at any time (if no deceptive intent)
- Need evidence of conception, reduction to practice, & diligence, and corroboration of each.

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What Constitutes Patentable Matter?

- Process: Business methods, software, advanced diagnostic medicine tests still patentable (with significant caveat).
- Machine (Perpetual Motion Machines specifically excluded)
- Article of Manufacture
- Composition of Matter

Living Matter?

- Microorganisms - 'A live, human-made micro-organism is patentable subject matter under § 101.
- Transgenic animals, knock-outs, etc.
- Humans - 'Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.' America Invents Act (AIA)
- Genes? cDNA? - *A naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but cDNA is patent eligible because it is not naturally occurring.* (Association for Molecular Pathology vs. Myriad Genetics, Inc.)

Novelty (§ 102): An Invention is Not Novel If It Was:

- Patented, published, known or used by **another** before your invention was made
- In public use, on sale, or published more than one year before your filing date (so called “statutory bar”)
- Described in a patent or application by **another** w/ a filing date earlier than your invention date
- Invented by **another** before your invention

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Nonobviousness (§ 103)

- Obviousness means that the invention is different from the prior art, but the differences are so trivial as to be “obvious to one of ordinary skill in the art.”
- Requirements are (a) a teaching of each element in the prior art; (b) a motivation to modify the prior art to arrive at the invention; and (c) a likelihood of success in making and using the invention.

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Secondary Considerations

Even if all elements are found, such “*prima facie*” obviousness can be overcome by “secondary indicia” of **non**-obviousness:

- commercial success
- long-felt need/failure of others
- unexpected advantages
- unexpected difficulties in achieving

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Utility (§ 101)

- Only need **some** practical utility (*e.g.*, entertainment); usually not a major issue.
- Specific exclusions for products of nature, perpetual motion machines, and those inventions that are contrary to public policy.
- Areas where you sometimes see such rejections are in human therapy and methods involving pure mental steps.

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Enablement & Written Description (§ 112)

- Enablement requires that a patent application teach how to make and use the full scope of the claimed invention.
- Written description requires evidence in the application of possession of the invention as claimed.
- It also must disclose the “best mode” for making and using the claimed invention.

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- License
- Option
- Material Transfer (MTA)
- Confidentiality (CDA, NDA)
- Inter-Institutional (IIA)
- Stockholder and Stock Purchase
- Collaborative Research (CRA)
- Sponsored Research (SRA)
- Clinical Trial (CTA)
- Data Use (DUA)
- Memorandum of Understanding/Letter of Intent (MOU/LOI)
- IP Assignment
- Visiting Scientist

Hints for Reading Agreements

- You don't have to start at the beginning and read through to the end.
- Start with the clauses most relevant to the business at hand
 - Grant
 - Licensed technology
 - Field of use and territory
 - Money
 - Diligence
 - IP protection
 - Termination

What is a license?

- The grant by the owner of intellectual property to another party of any of the rights embodied in the IP short of an assignment or sale of all rights.
 - Without this grant, the other party would be infringing the owner's rights and thus be in violation of the law.
- Academics generally do not make products; they grant rights in IP to a commercial organization for further development and sale of the resultant product (Licensed Product).
- License terms are found in multiple places, e.g. MTA's and SRA's.

What can be licensed?

Anything you can think of!

- Patents
- Copyrights
- Trademarks
- Know-how
- Technical information
- Tangible Property

Term Sheet – The Supporting Framework

- Royalty
- Upfront payment
- Annual minimum royalties (usually creditable against actual royalties, but the credit should apply only to the year the royalties were earned.)
- Patent Expenses (past and future)
- Milestone payments
- Annual license maintenance fees
- Field of use
- Exclusivity
- Grant back
- Infringement conditions
- Term and Termination
- Sublicense and share
- Gov't rights
- Indemnity and Insurance

Grant

- **The most important section of the document!**
- **What is being granted, i.e. what rights are being conveyed:**
 - Right to make, have made, use, lease, offer to sell, sell and import the Licensed Product...
 - Within the licensed Field
 - Within a specific Territory or worldwide
 - Rights retained by government.

Field of Use

- Disease or indication
- Research or commercial
- Diagnostic or therapeutic
- Human or veterinary or plant
- *In vivo or in vitro*
- Military or civilian
- Industry or product specificity e.g. automotive vs. aviation; turbine vs. gas engine

Grant part II

- What type of license?
 - Exclusive
 - Non Exclusive
 - Internal research only
 - Exclusive by field or territory
 - Limited or Co-Exclusive (Rare)
 - Often exclusive for Patent Rights; non-ex for tangible research products, software.

Grant part III

- Grant Back to Licensor Institution
 - Use for research and education purposes.
 - Use by other institutions for research and education purposes.
 - May publish and disseminate scientific findings from research related to invention.
 - License to some of Licensee's IP.
 - Related IP developed by Licensee.

Know-how

- Be careful here.
- **Best practice – never license know-how exclusively.** You could end up with the inventors not being able to use their own know-how or not being able to convey know-how to collaborators, etc.
- Particularly important in field of use licenses.
- You will get push-back, but stand your ground.

Improvements

- Almost always a sticking point in negotiations.
- Companies generally want all improvements included in the license without having to pay for them.
- In the event a new discovery is made relating to the subject invention or an improvement is made to the invention under this license agreement, company receives the first chance to negotiate a license to the new discovery or improvement (first option).
- The first option should be limited in scope and duration.
- What does “relating” mean?
- First Option is different than a Right of First Refusal.

Development Plan

- The plan that the company agrees to follow while taking your IP along the path to \$\$\$\$.
- Reasonable to ask for one prior to negotiating the license, particularly if doing a deal with a small or startup company.
- There should be readily identifiable development milestones.
- Reports should be frequent enough that you are kept informed, but not so frequent as to be overly burdensome to the company.
- Milestones, reports, etc. should be tied to termination provisions.

Diligence

- Licensee agrees to, throughout the term of this Agreement, use its best efforts to develop, manufacture, promote and sell Licensed Products and to perform any Licensed Services, in each instance throughout the Territory and in the Field.
- What does “commercially reasonable efforts” mean?
 - What is commercially reasonable to you may not be the same as what’s commercially reasonable to the company.
 - It may be commercially reasonable to the company to shelve your technology in favor of something else. However, the tech transfer office would not define that as reasonable.

Diligence Pt. II

- Diligence is often another sticking point.
- You have to be able to get the technology back if the company is not developing it in accordance with the license.
- The company does not want to have the rug pulled out from under it.
- Tools to be used to encourage product development:
 - Annual license maintenance fees that are large enough to hurt if the company has to pay for something it is doing nothing with.
 - Payments associated with missing milestones.
 - Breach and termination.

MTA's - Corporate

- Corporate MTA's are usually fairly restrictive – they have put a lot of money into developing the materials and need to protect their investment.
- Publication – ok to give the provider of the material a reasonable period of time to review manuscripts for confidential information and patentable matter.
- Company should not have approval rights over any publication or presentation, but it is fair to require removal of the company's confidential information. Be careful about how CI is defined – you don't want it to be everything.
- Company will probably want to own IP resulting from use of their materials and will almost certainly want to own it if the materials are used for something outside the research project for which they are sending the materials (not unreasonable).

IP Rights and Licensing in Corporate MTA's

- Try to narrow IP rights to modifications of a compound or something narrow enough that if the investigator has a major Ah-Ha moment, the institution can capture some value.
- NERF: the company will want a non-exclusive royalty-free license to any IP developed through use of their material.
 - These are the bane of tech transfer offices' existence.
 - Often little incentive for the company to enter into a royalty-bearing exclusive license.
 - Investigator often does not care about this and wants the material regardless of downstream consequences.

First Option for an Exclusive License

- An exclusive license should be royalty-bearing.
- Reasonable length of time for the company to decide/exercise should be included – the shorter the better so you can find another licensee if appropriate.
- Reasonable length of time for negotiation of the deal is also needed.
- Good faith negotiations; terms based on industry norms.
- Most favored nations.

MTA's - Academic

- Usually easier than corporate MTA's.
- UBMTA.
- HHMI.
- Ok to ask for proper attribution in papers, reasonable shipping costs to be covered.
- Be careful about allowing licensees to dictate what can be in MTA's.
 - Inventor needs to be able to share materials with colleagues.
 - May run afoul of NIH sharing requirements.
 - You may get a reputation for being difficult (whether or not deserved).

CDA's

- The time requirement for keeping information should be reasonable. If you're receiving the information, the shorter the better.
- When providing information, make sure there is a non-use provision. In some ways, this is the most important part of the CDA.
- Try to define the information to be exchanged as specifically as possible. This will make the agreement more enforceable.
- Require written materials to be marked as confidential.
- Reduction of verbal exchanges to writing – tough to get investigators to do this.



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Post-grant Proceedings under the AIA- How Do They Affect My University?

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- August 12
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- October 1

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alliance of technology transfer professionals

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For more information about the registration process and requirements, visit the Alliance of Technology Transfer Professionals website.

www.attp.info

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Baltimore, MD USA

AUTM Western Region Meeting

Date: Oct. 2 – 3, 2014

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Oct. 13 – 14
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Sept. 23 – 24
Hosted by Wake Forest Innovations
Winston-Salem, NC USA

AUTM Business Development Course

Nov. 12 – 13
The Westin O'Hare
Rosemont, IL USA



Save the Date!



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AUTM Annual Meeting



AUTM 2015 Annual Meeting

Feb. 22 – 25

New Orleans, LA USA



Save the Date!

