Bench to Bedside: Translating Academic Research Into Commercial Products

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UNC | INNOVATION, ENTREPRENEURSHIP AND ECONOMIC DEVELOPMENT
Technology Commercialization

Goals of the Office of Technology Commercialization

- Maximize impact and enable full potential of academic research
- Social benefit/responsibility
- Generate revenue to further enable research and educational programs through licensing and/or sponsored research
- Reward inventors/departments to incentivize further innovation
- Economic development for region through startup formation and/or collaboration with local industry

Examples of “Real World” Inventions Arising from UNC Research

- New Drugs (small molecules)
- Biologic Therapeutics: monoclonal antibodies, protein/peptide therapeutics
- Cell & Gene Therapies
- Vaccine Design
- Medical Devices/Imaging Technologies
- Software
- Improvements for Virtual Reality, Gaming, etc.

https://www.unc.edu/posts/2017/06/07/predicting-autism/

DISCOVER NAVIGATE SEARCH THE UNIVERSITY *of* NORTH CAROLINA *at* CHAPEL HILL News and

HEALTH AND MEDICINE

Predicting autism

University of North Carolina at Chapel Hill researchers and colleagues linked infant brain anatomy differences to autism diagnoses at age two. Now they show differences in functional connections between brain regions at 6 months to predict autism at age two.

By UNC Health Care, Wednesday, June 7th, 2017

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NEWS / Pfizer Doses First Patient Using Investigational Mini-Dystrophin Gene Therapy for the Treatment of Duchenne Muscular Dystrophy

PFIZER DOSES FIRST PATIENT USING INVESTIGATIONAL MINI-DYSTROPHIN GENE THERAPY FOR THE TREATMENT OF DUCHENNE MUSCULAR DYSTROPHY

Thursday, April 12, 2018 - 8:00am EDT

Pfizer Inc. has initiated a Phase 1b clinical trial for its mini-dystrophin gene therapy candidate, PF-06939926, in boys with Duchenne muscular dystrophy (DMD). The first boy received an infusion of the mini-dystrophin gene on March 22nd, administered under the supervision of principal investigator, Edward Smith, MD, Associate Professor of Pediatrics and Neurology at Duke University Medical Center. Screening and enrollment of patients is expected to continue at up to four clinical research sites in the United States. Early data from this trial are expected in the first half of 2019, once all patients have been evaluated for one full year post-treatment.

"On behalf of the community of individuals and families living with Duchenne muscular dystrophy, we applaud the important step Pfizer has taken to advance a potentially transformational treatment option for boys stricken with this terrible disease," said Debra Miller, CEO and Founder of Cure Duchenne. "The momentum we are seeing in the field of gene therapy emphasizes the maturing opportunity to advance the science. Today, there are very limited treatment options for our boys. Through collaboration and ongoing dialogue with companies like Pfizer, we hope to succeed in finding therapies that could dramatically change the outcomes for those with DMD."

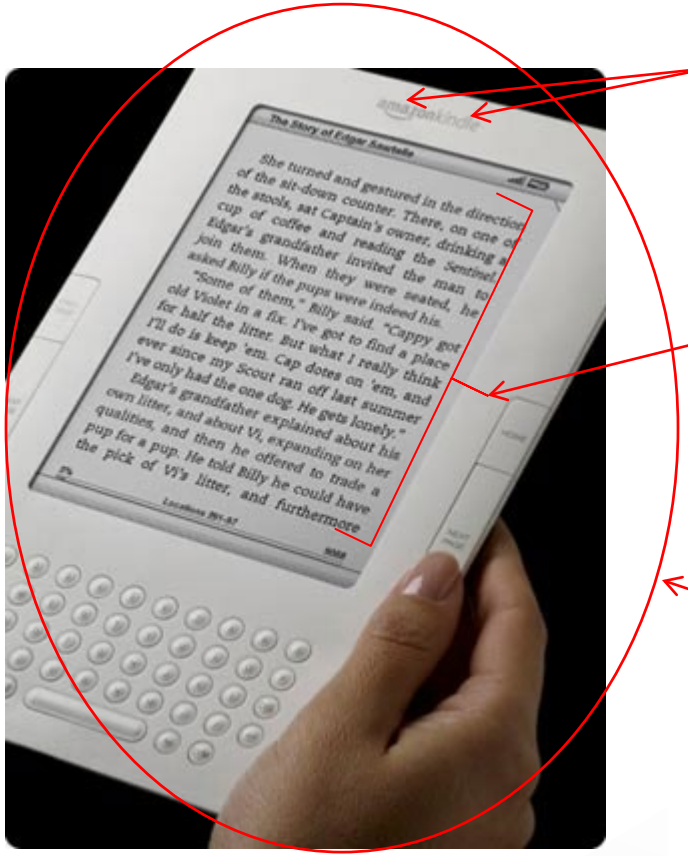
Functions of Technology Commercialization Managers

Manage	• Invention disclosure process
Identify	• Technologies with commercial potential
Pursue	• Intellectual property protection
Market	• Technologies to companies
Navigate	• Laws, policy and contractual obligations
Negotiate	• Contracts to license rights
Ensure	• Diligent development of products
Reinvest	• Proceeds into research
Monitor	• Licenses for up to 20 years

What Does the Office of Technology Commercialization Handle?

- Technology Assessment & Commercialization
  - Patent Filing and Prosecution
  - Inter-institutional Agreements
  - Option/License Agreements
- Limited Collaborative Research Agreements (only those without funding)
- Intellectual Property Terms in Commercial Sponsored Research Agreements – collaborate with OSR as needed, on a case-by-case basis
- Material Transfer Agreements – both academic and commercial
- Confidentiality Agreements (in addition to OSR & OCT) – when related to intellectual property

Intellectual Property: *"A property right created by law to protect intangible assets"*



Trademark protects words, names, or symbols used in commerce

Copyright protects original works of authorship (text, artwork, music, computer code)

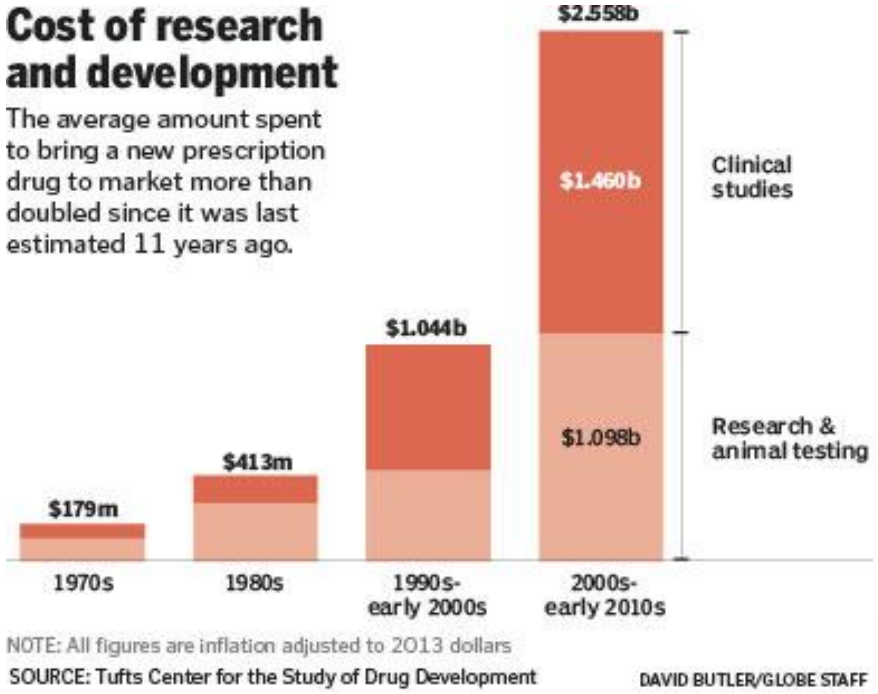
Patent protects process, machine, article of manufacture, or composition of matter

Tangible Property: “A Physical Property Right”

- Common Examples: mouse models, cell lines, antibodies, proteins
- Tangible Property Licenses:
  - Grant the right to possess and reproduce the material - depending on situation either for internal R&D or for sale
  - Allows for broader distribution and incorporation into other useful products
  - University can stay out of day-to-day production and shipment of material

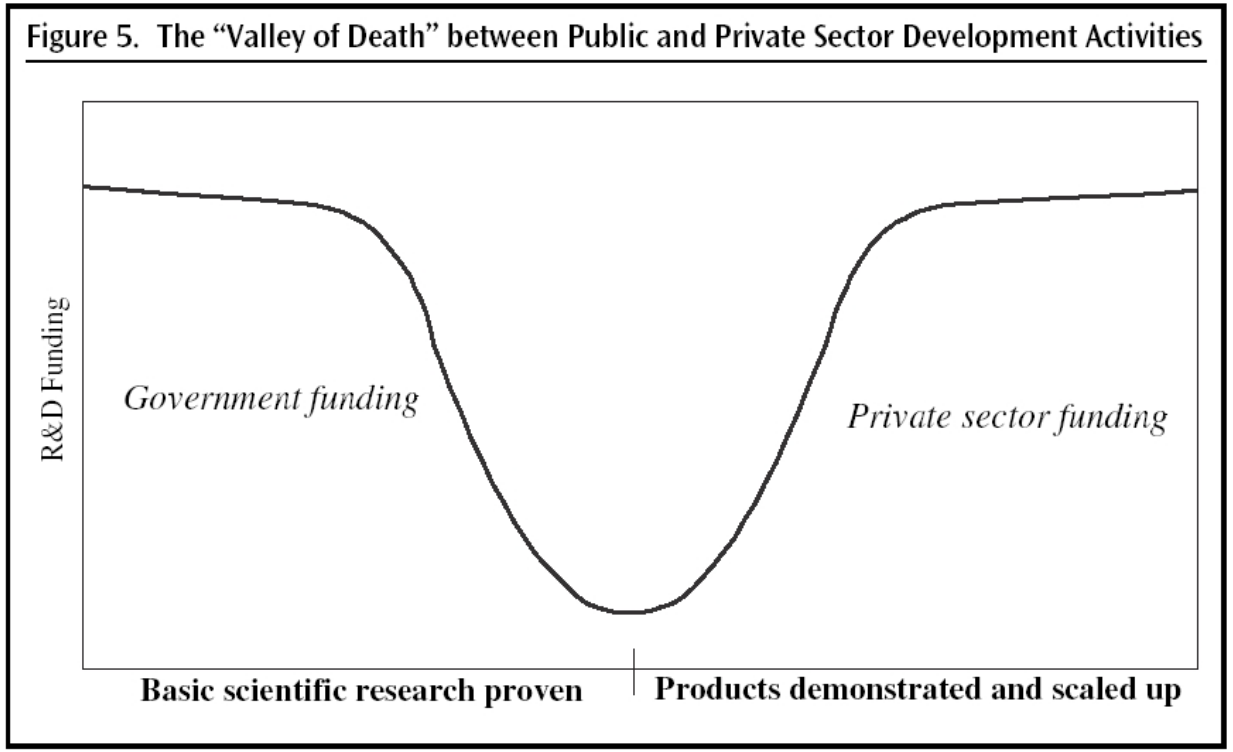
Why patent?
Why should a university patent?
Why not encourage the free flow of knowledge?

Importance of Exclusivity



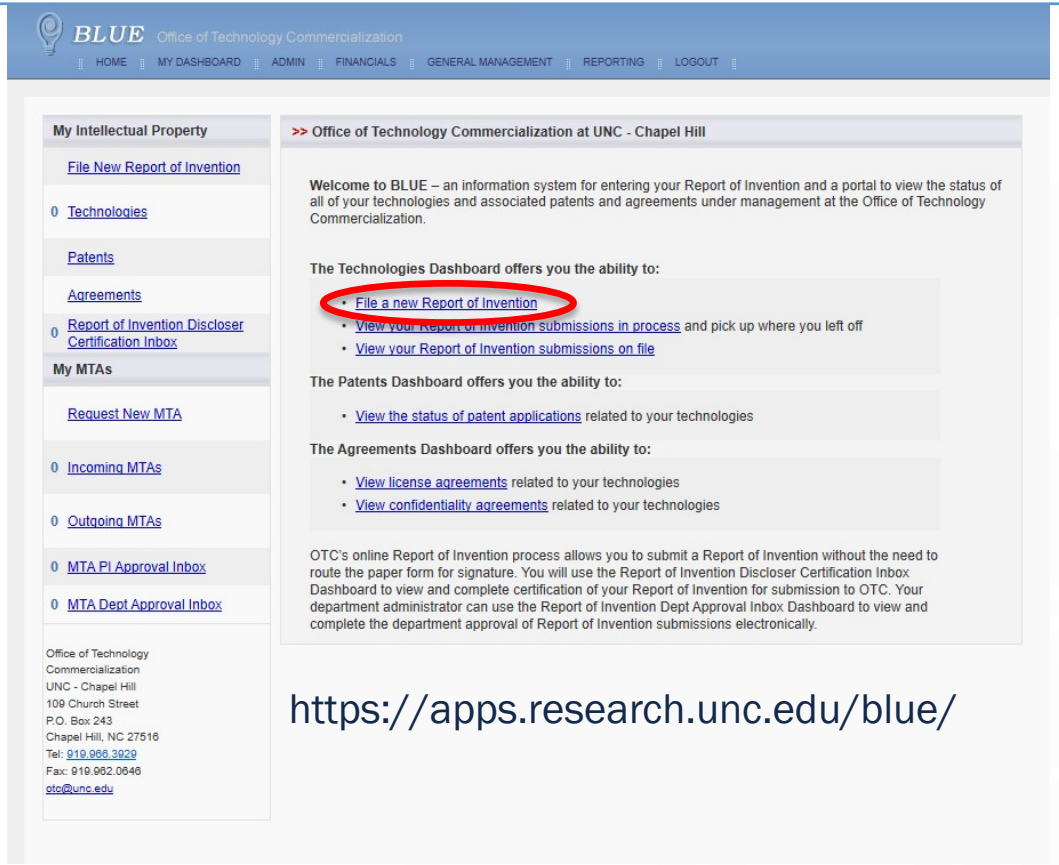
Will academic discoveries make it to the marketplace without patent protection?

The “Valley of Death”



World Bank Working Paper No. 138

Submitting an Invention Disclosure in BLUE



https://apps.research.unc.edu/blue/

Appropriate Timing of an Invention Disclosure

AT LEAST 30 DAYS PRIOR TO ANY PUBLIC DISCLOSURE OF A POTENTIALLY PATENTABLE IDEA

Invention Development Stage	Timing of ROI
Innovation: Idea	Premature
Conception: How to do it	Good
Reduction to Practice: Make it work	Best
Preparation of a Paper: Describe it	Good
Immediately Prior to Public Disclosure	Poor: may not have time to prepare a useful patent application
Post-Publication or Disclosure	Poor: foreign patent rights lost

ANYTIME BEFORE OR AFTER PUBLIC DISCLOSURE OF TANGIBLE PROPERTY

What is a Public Disclosure?

- Any public presentation counts as a public disclosure
- Grant applications (most) and UNC internal meetings (most) do not count as a public disclosure
- Meetings for which a confidentiality agreement have been put in place do not count
- Submit your invention disclosure to OTC before publication (Alert OTC if disclosure is imminent.) Note: Dissertations are published!
- It is ok to submit an invention disclosure within one year after publication. If US rights are of value, OTC may still consider filing

*Submitting an Invention Disclosure does NOT offer protection. A patent application must be on file with the USPTO before protection is in place.

Material Transfer Agreements (MTAs)

Purpose: When receiving or providing research materials, MTAs govern how those materials may be used by the recipient and their institution/company and how results and intellectual property arising from such research with these materials will be managed.

Who: In addition to managing intellectual property, OTC is the resource at UNC for negotiation and signature for all unfunded MTAs except for the following:

- Data usage agreements
- MTAs that involve transferring PHI or prospective collection of patient samples
- MTAs where clinical/patient treatment decisions will be made based on information/materials exchanged

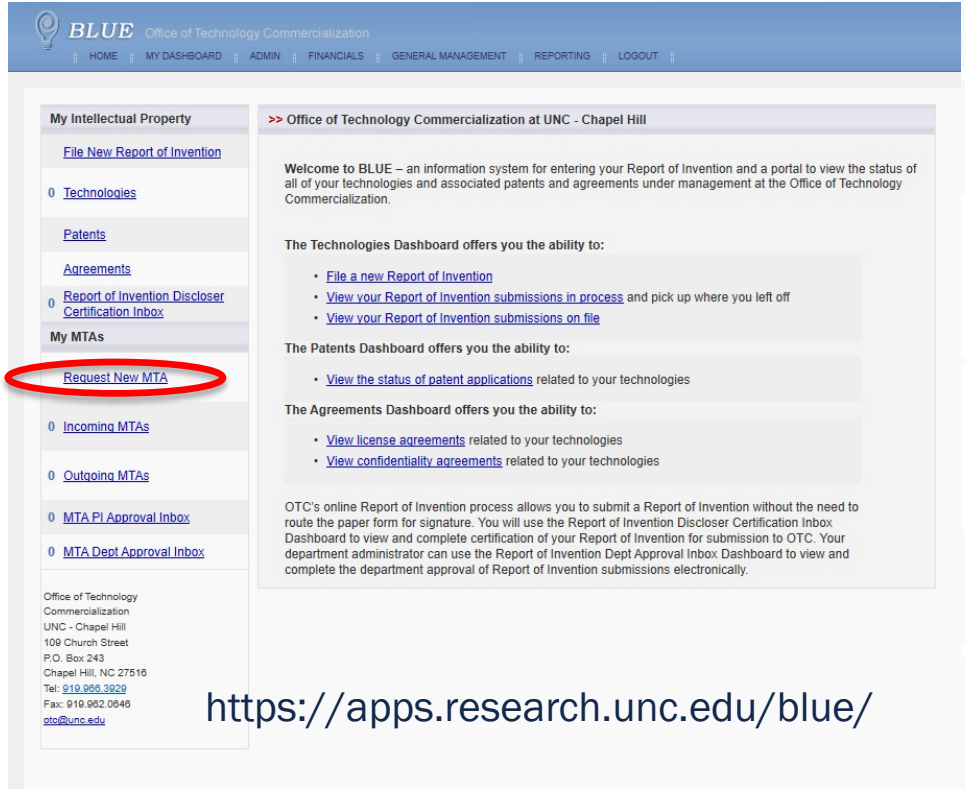
*These exceptions are handled by the Office of Industry Contracting.

Reimbursement of Costs: Only allowed to the extent such monies are for the preparation and shipment of the materials being sent. If there is an exchange of funds over and above the cost of providing the materials then it would be a sponsored research agreement (SRA) or service agreement. Departments are responsible for invoicing for charges related to MTAs.

Requesting a Material Transfer Agreement

How: Submit MTA Request Online in BLUE

- MTA requests (incoming and outgoing) must be submitted online
- Providing funding information promptly and other requested information related to the transfer will move the MTA along faster
- If request is for outgoing human-derived material, IRB approval is required and OTC will need copies of the informed consent template.
- Certain provisions may require department approval prior to execution
- Correspondence related to MTAs can be sent to mta@unc.edu



https://apps.research.unc.edu/blue/

Do I need an MTA? The answer is YES if…

Incoming Material

- The providing party requires an MTA

Outgoing Material

- Providing material to a for-profit company

- Material is subject to hazardous use restrictions

- Material is human tissue being distributed (with IRB approval or exemption) to parties independent of a clinical trial or clinical research agreement

- Creation of the material at UNC was funded by an agency that mandates special restrictions on material generated under the funding agreement

- Material is the subject matter or is related to a technology for which UNC has filed patent applications or which the PI intends to commercialize

- Even if the above don't apply, MTAs can still be executed at your request

Confidentiality Agreements (CDAs) (also known as Non-Disclosure Agreements (NDAs))

Purpose: In some circumstances, confidential information must be exchanged in order for the University and an outside partner to determine whether to enter into a collaboration or contract. In such cases, CDAs may be signed which outline the terms under which such confidential information will be exchanged.

Who: OTC has signatory authority to sign CDAs related to existing IP on behalf of the university. If in relation to a sponsored project and not intellectual property, CDAs will be handled by OSR.

How: Contact OTC at 919.966.3929 or e-mail otc_cda@unc.edu

Having the following information ready will help us expedite your request:

- Name, organization, address, telephone, and e-mail address of the requesting individual
- Description of the subject matter to be disclosed
- Date of the proposed meeting/call

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BLUE: apps.research.unc.edu/blue/

MTA Questions: mta@unc.edu

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More information: otc.unc.edu or 919.966.3929