

Innovation Ambassador Program

Training Session #1: CTTC



VANDERBILT
UNIVERSITY

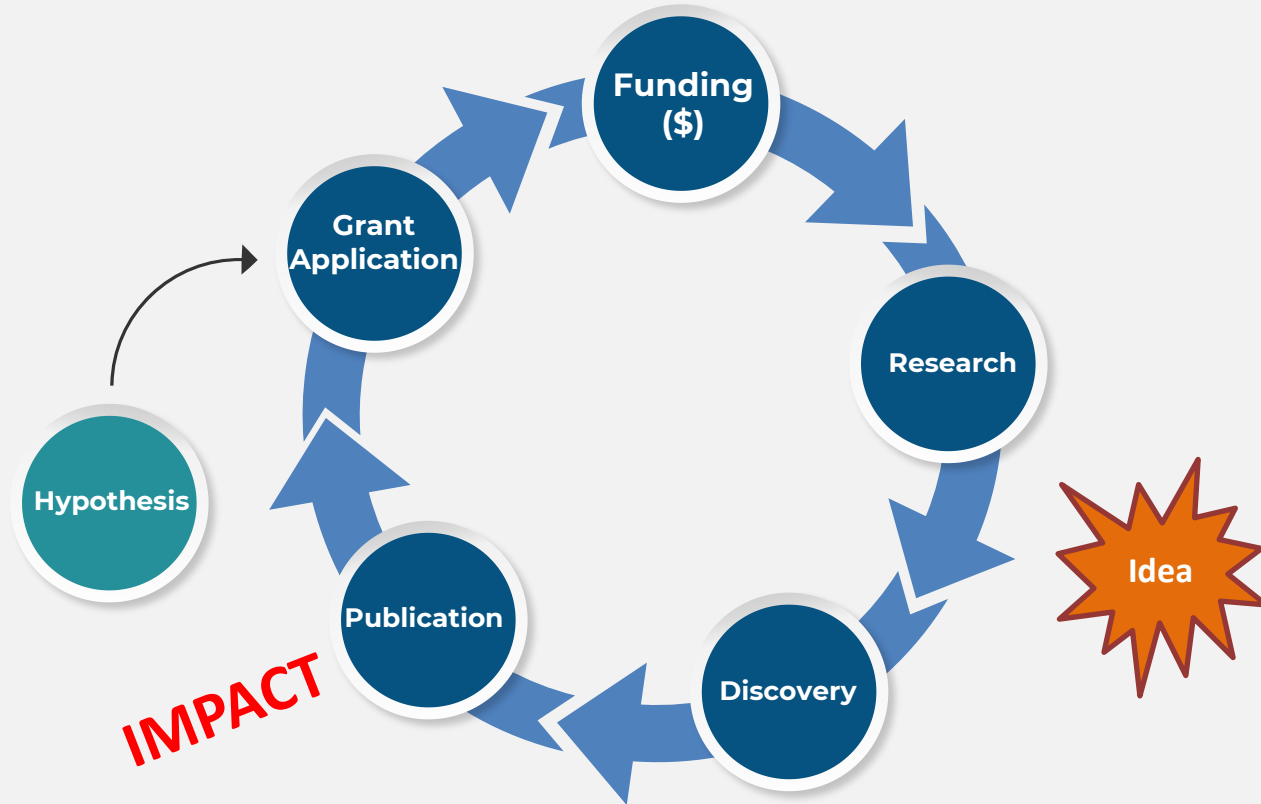
Technology Transfer



INNOVATION

it becomes critical during a recession

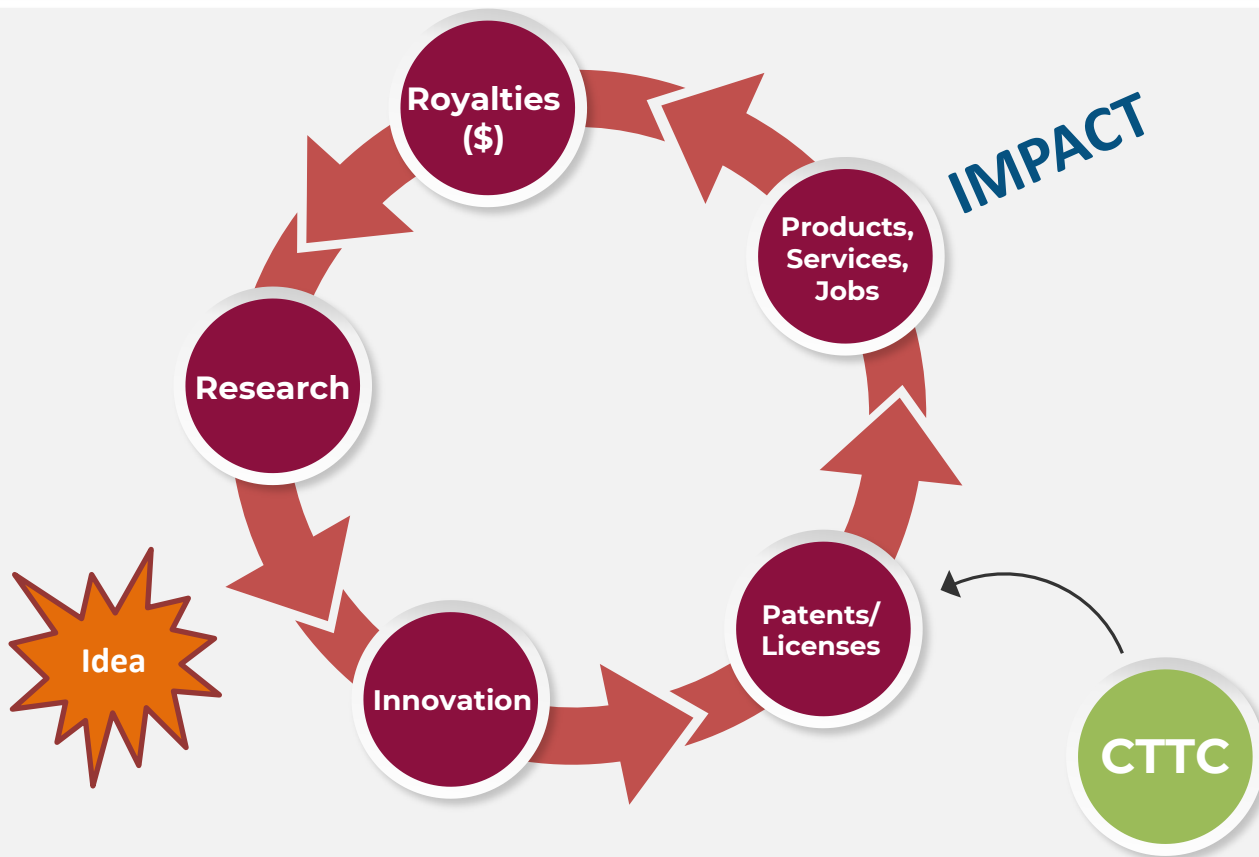
Academic Research Cycle



Innovation Cycle



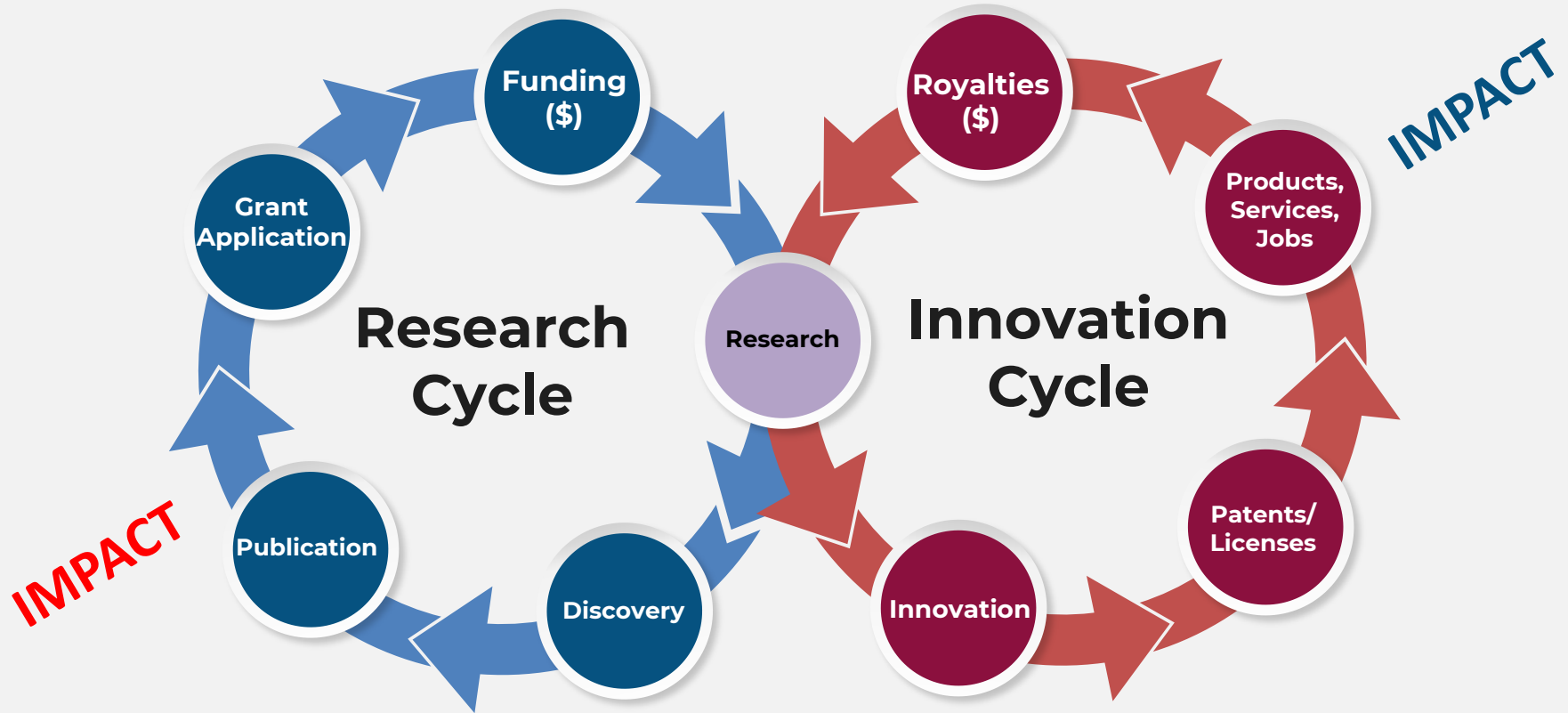
VANDERBILT
UNIVERSITY
Technology Transfer



Impact Cycles – not mutually exclusive



VANDERBILT
UNIVERSITY
Technology Transfer



CTTC Structure and Function

Serve the Vanderbilt community by assisting University inventors in *bringing their innovations to practical application for the benefit of the public*

Help ensure investigators' research achieves **IMPACT** in the world

**License
inventions to
industry**



**Help launch
new start-up
companies**

CTTC Faculty Services

**Business
development/
Industry
engagement**



**Research
support &
compliance**

Core Operations

- Technology evaluation, protection and licensing
- New venture assistance
- Assisting with securing research funding from industry
- Federal Government compliance (Bayh-Dole)
- Medical Products Support Services (MPSS)

Other Key Functions

- Material Transfer Agreement processing
- Education/training
- Industry research contract support
- Committee/board participation
- Strategic consultation for VU and VUMC

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(Competing) Objectives



- Reports to VU Vice Provost for Research
 - Dotted line reporting to VUMC EVP Clinical Research
- Services both University and Medical Center
 - Governed by VU-VUMC contract

Office Structure and Personnel



VANDERBILT UNIVERSITY
CTTC Center for Technology Transfer & Commercialization

Office of Vice Provost of Research

CTTC

Economic & New Venture Services

Operations

Licensing

MPSS

Corporate Contracts

- Assessment of business concepts for new ventures
- Entrepreneurial education and support
- Assistance with commercial grants, such as NSF I-Corps
- Review of business plans and financial models
- Assistance with identifying sources of capital, advisors, service providers
- Assist with management of equity from licensing and service on boards

Entrepreneur In Residence

- Funding sponsor/Federal Government compliance
- Managing intellectual property protection
- Metrics/activities reporting
- Internal/external outreach
- Revenue collection and distribution
- Management of agreements and legal documents
- Data collection, curation management
- Online licensing store
- Systems Development

BioTechnology

- Evaluation of new inventions
- Protection of new inventions
- Marketing of technology to industry
- Alternatively, supporting the creation of new ventures to commercialize technology
- Drafting, negotiating and executing technology license agreements and confidentiality agreements
- License compliance monitoring

Digital Technology

Engineering and Physical Sciences Technology

- Assisting in commercialization of medical devices and pharmaceuticals
- Providing counsel in regulatory support of R&D
- Facilitating interactions with and review by IRB
- Assisting with compliance with FDA design control regulations
- Advising on medical device FDA product type categorization

- Drafting and negotiating MTAs with academic institutions and corporate partners
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- Management of contracts
- Reports metrics on transaction turn-around times

Office Structure and Personnel



VANDERBILT UNIVERSITY
CTTC Center for Technology Transfer & Commercialization

**New Ventures
 (4 employees)**

Office of Vice Provost of Research

CTTC

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CTTC Center for Technology Transfer & Commercialization

Office of Vice Provost of Research

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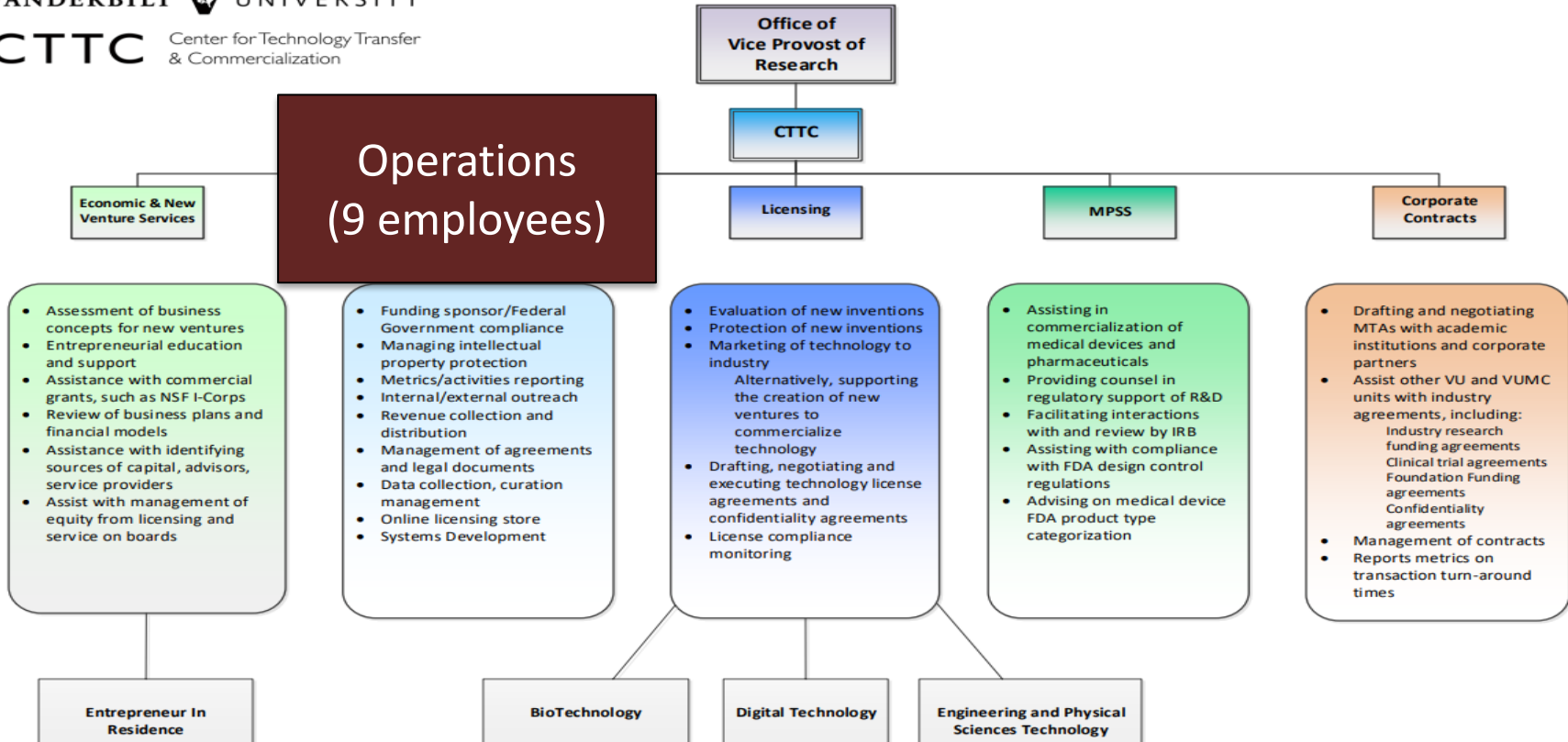
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BioTechnology

Digital Technology

Engineering and Physical Sciences Technology

Office Structure and Personnel



Office Structure and Personnel

Office of
Vice Provost of
Research

Licensing
(12 employees)

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Healthcare Team

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Research

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Digital Tech
Team

Entrepreneur In
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BioTechnology

Engineering and Physical
Sciences Technology

Office Structure and Personnel

Office of
Vice Provost of
Research

Licensing
(12 employees)

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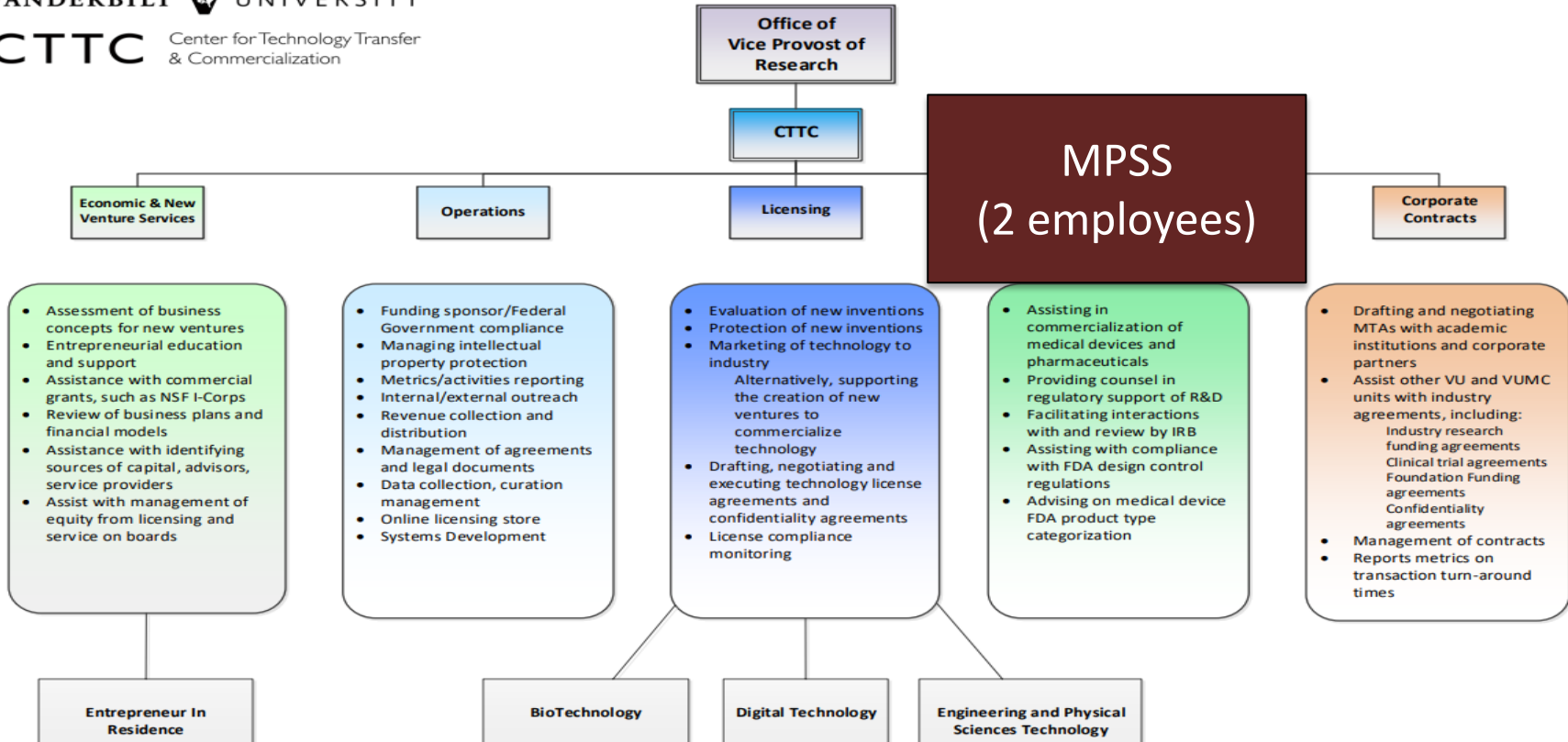
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Physical Sci. and
Engineer. Team

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Office Structure and Personnel



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Office of
Vice Provost of
Research

CTTC

Economic & New
Venture Services

Operations

Licensing

MPSS

Corp Contracts
(3 employees)

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- More than 180 years combined licensing experience
- Insights and experience from Johns Hopkins, Cleveland Clinic, UVA, Wake Forest, NREL, ORNL, Fred Hutchinson Institute, Blood Center of Wisconsin, WashU, and University of Illinois
- Industry experience from Abbott, Millennium, Bridgestone, Infinity Pharma, Gaylord, Genaera Corp. + 2 startups
- 3 patent agents and 1 patent attorney on staff
- 1 MD on staff as Medical Director and head of MPSS

Industry Collaborations

- CTTC tracking Industry Sponsored Research stemming from licensing since 2013
 - Impact: greater than \$20M annually
- 2022: University decision to create a new unit under the VPR's office focused on industry engagement
- Chris Rowe (VUSE) chosen to build Industry Collaborations team and lead effort
 - Team to build slowly over FY23 and FY24
 - Co-located with CTTC
 - Serves both VU and VUMC – coordinates with VUMC efforts
 - Enhance existing industry relationships
 - Forge new industry relationships
 - Coordinate efforts with local, regional and statewide stakeholders



New focus on entrepreneurship services

VENTURE LAUNCH

ABOUT US

Advanced support services for new ventures licensing Vanderbilt IP and/or securing Vanderbilt investment.

Evaluation assistance

Business Modeling

Startup-friendly licensing

Formation services

Governance assistance

Assistance with access to capital

KNOW MORE



48

Startups
Created

99M

Capital
Raised

3

ENTREPRENEURSHIP SERVICES



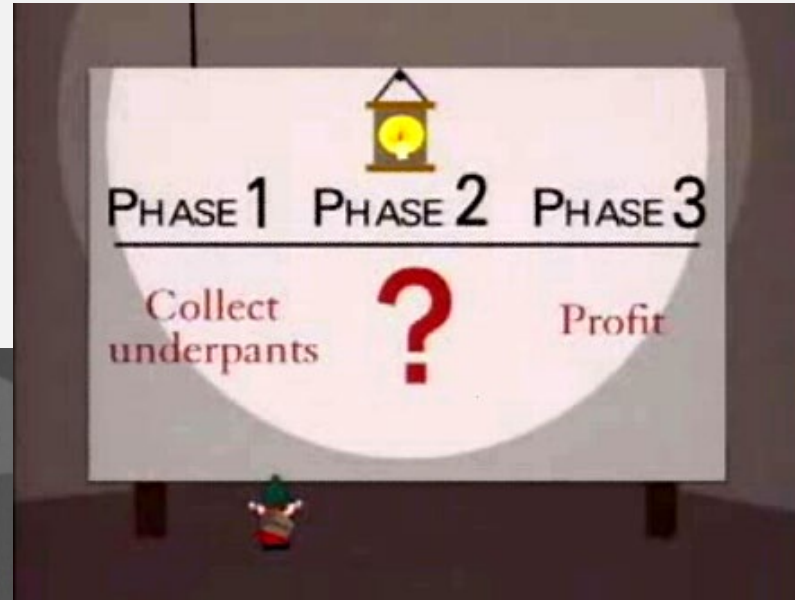
Staging and Development:

Formation of a roadmap for the new venture, including development of a business model and presentation materials.

- Develop the Business Roadmap
- Refine the financial model
- Refine the business plan
- Modify pitch decks for multiple uses



Importance of a Cohesive Biz Plan



Exemplary CTTC Programs



CTTC Publications & Communications



VANDERBILT UNIVERSITY
CTTC Center for Technology Transfer & Commercialization

TECH CONNECT
Turning Ideas into Opportunities

About CTTC | For Faculty | For Industry Licensees | Entrepreneurship/ New Ventures

Monthly news & updates June 1, 2021

FY 2021 STATISTICS
YEAR TO DATE

Licenses*/Options 225	CTTC commercialized 25 COVID-19-related discoveries, facilitated nine startups during a record-setting year
MTAs 1,024	
CDAs 59	
Invention Disclosures 154	

The Center for Technology Transfer and Commercialization continued to play a pivotal role in translating the research findings of Vanderbilt faculty into products and companies in 2020. Amid the myriad challenges of that year, CTTC successfully evaluated, marketed, and licensed new inventions, conducted investor pitches and facilitated startup formations, executed material transfer agreements and sought issuance of patents for Vanderbilt innovations, all at levels equal to or surpassing earlier years. These



Monthly, CTTC updates

VANDERBILT UNIVERSITY
VANDERBILT VENTURE LAUNCH TURNING IDEAS INTO OPPORTUNITIES

SUMMER 2022 NEWSLETTER

VANDERBILT STARTUP CLOSING LATE SEED ROUND
HEROWEAR RAISING \$2M ROUND

HeroWear, a Nashville-based wearable technology company, is finishing up a late seed round of financing to expand its product sales and distribution capabilities in advance of a larger financing round planned for early 2023. The company sells a super light weight biomechanical exosuit-branded Apex™ - that reduces fatigue and musculoskeletal strain on workers while lifting and moving objects, and has eclipsed \$1M in revenue in its first full year of sales.

The base exosuit was developed in the Vanderbilt Center for Rehabilitation Engineering and Assistive Technology ("CREATE") by Karl Zelik and a team of graduate students and colleagues. The CREATE lab's mission is to improve health and mobility and to enhance human performance and well-being through advances in movement science and assistive technology.



The Apex™ device (pictured above) is performing admirably. The company is expanding its customer base and Apex™ has received strong reviews from customers. HeroWear is also evaluating other assistive technologies that would expand the company's product offerings.

NEW VENTURES TEAM

The mission of the CTTC new ventures team is to facilitate the formation of new ventures powered by Vanderbilt technology. Our objective is to be the principal partner for our faculty, staff, inventors and entrepreneurs who are exploring new venture opportunities. Our engagement model helps university inventors and entrepreneurs to better understand the new venture creation process - from ideation to formation.

PETER ROUSOS
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DIRECTOR, ECONOMIC AND NEW VENTURE DEVELOPMENT

GEORGE WILSON
george.wilson@vanderbilt.edu
ASSISTANT DIRECTOR, NEW VENTURES PROGRAMS

HEATHER KACHINKO
heather.kachinko@vanderbilt.edu
COORDINATOR, NEW VENTURES

CTTC
Center for Technology Transfer & Commercialization

Quarterly, new venture updates

VANDERBILT UNIVERSITY
CTTC Center for Technology Transfer & Commercialization



DRIVING INNOVATION FORWARD

FALL 2021

Yearly, CTTC highlights

Reputational Impact of Technology Commercialization Efforts



World's Most Innovative Universities | 2017

Top University Rankings

#10 Vanderbilt University USA

Website: www.vanderbilt.edu

Students: 12,587



TOP 10

THE WORLD'S MOST
INNOVATIVE UNIVERSITIES

by Thomson Reuters



TOP 100
WORLDWIDE UNIVERSITIES
GRANTED U.S. UTILITY PATENTS
— 2017 —



NATIONAL ACADEMY OF INVENTORS



Intellectual
Property
Owners
Association

FierceBiotech

BIOTECH RESEARCH CRO MEDTECH

Attend the FierceBiotech 3rd Drug Development Forum!

The leading executive-level forum for biotech strategy & networking | Oct 1-3 | Boston

Research

Boehringer, Vanderbilt University to develop cancer M inhibitors in third team-up

by Angus Liu | Mar 15, 2018 9:58am



Vanderbilt and Lundbeck to Develop a Novel Approach for Treating Schizophrenia

NEWS | Jan 10, 2018 | Original story from Vanderbilt University



New Approach to Schizophrenia Treatment

The Vanderbilt compounds have been shown
in animal models to block dopamine release
in several key brain regions...

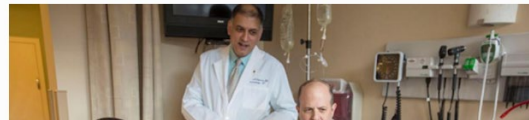
Can Cancer Care Be Industrialized? Vanderbilt And GE Are Teaming Up To Find Out



Ellie Kincaid Forbes Staff

Healthcare

Assistant editor covering medicine and health care.



VUMC Reporter

Management, Vanderbilt University Launch of Ancora Innovation

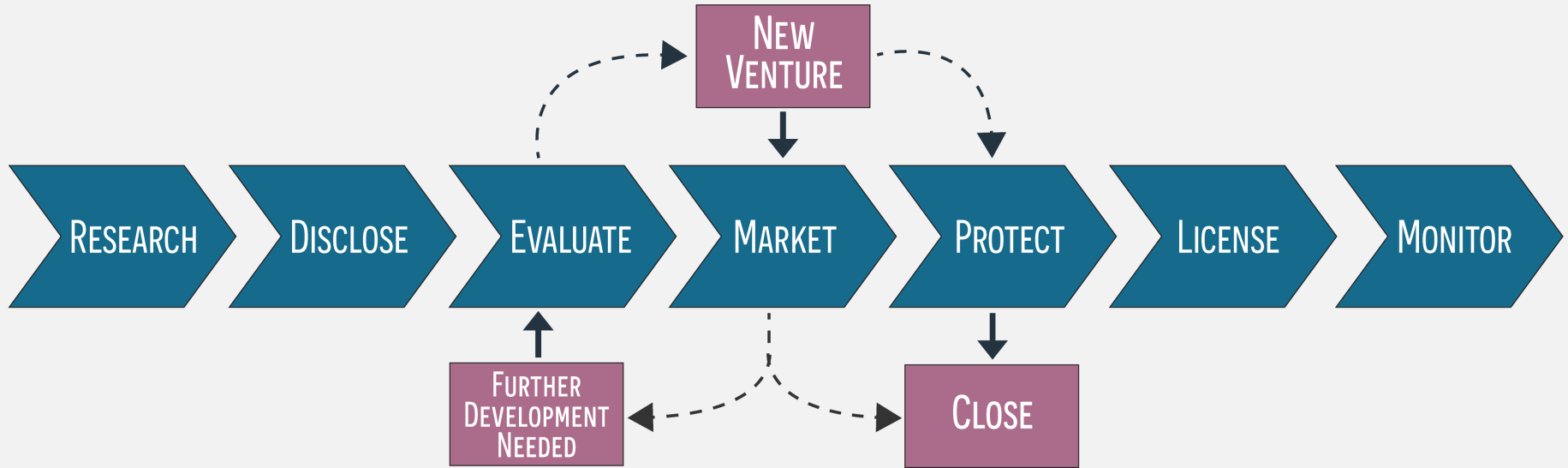
Vanderbilt University announced
Ancora Innovation, LLC ("Ancora"), a
joint venture to support Vanderbilt's innovative life
science research. Ancora will leverage
Deerfield's expertise in
drug development. Ancora will
be changing the current paradigm of
developing novel therapeutics to cure



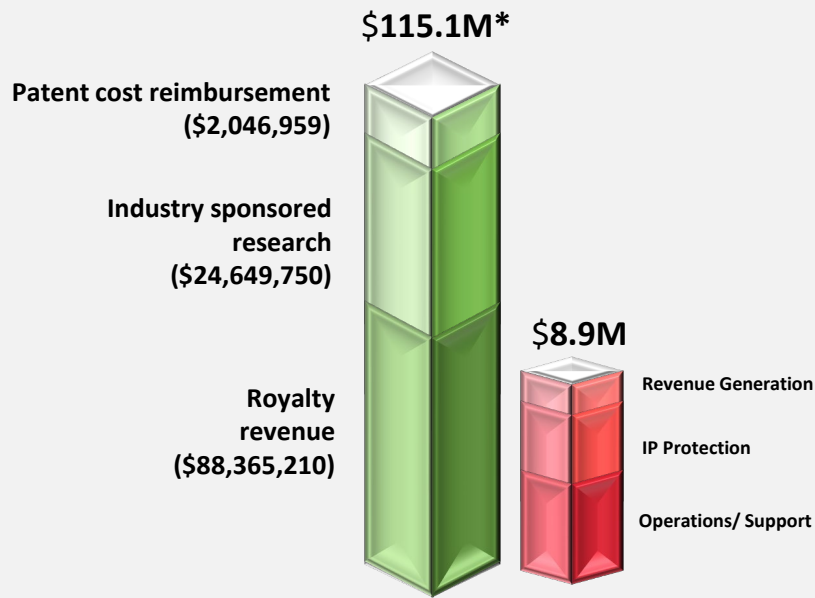
(Stock)

CTTC process and metrics

Commercialization Process



FY22 Impact

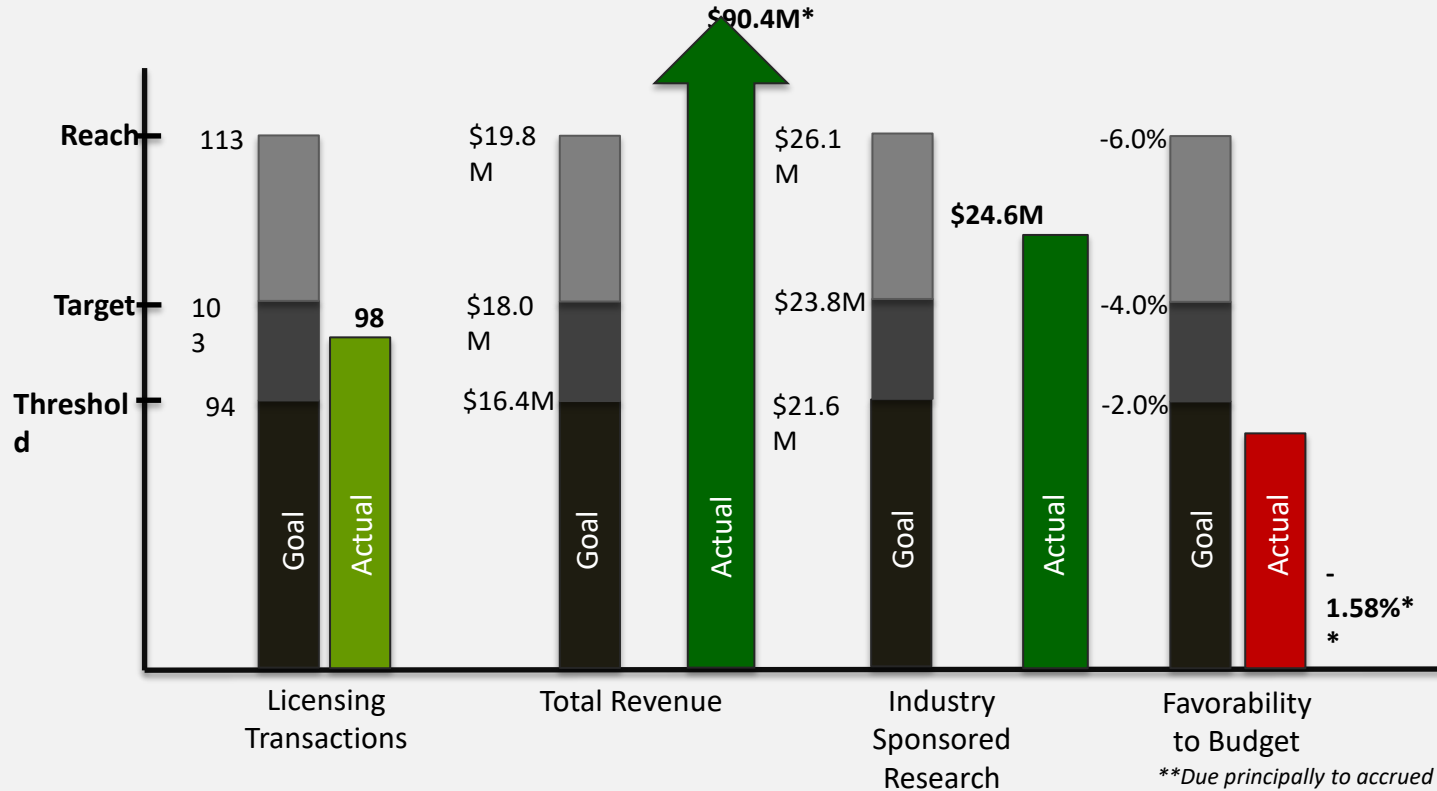


FY 2022

Invention Disclosures Reviewed	165
U.S. Patents Issued	60
License Agreements Executed	98
New Startup Companies Formed	2
Total Licensing Revenue	\$90.4M*
Research Support from Industry	\$24.6M*

**Results based on cash received in the fiscal year*

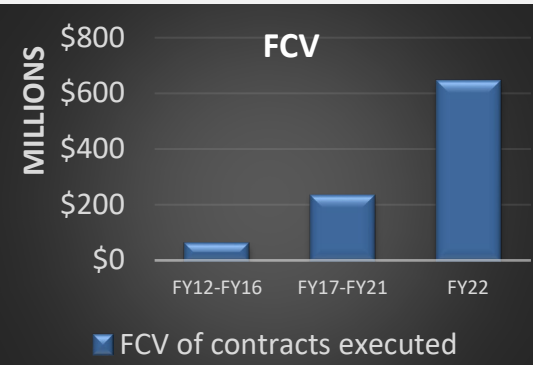
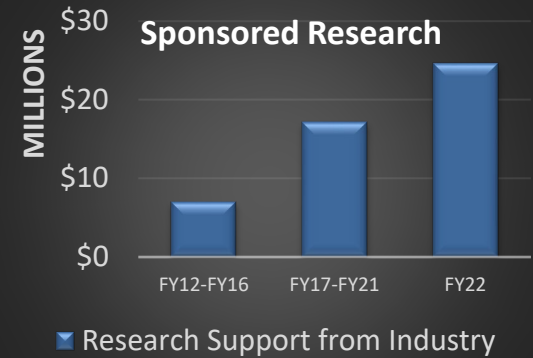
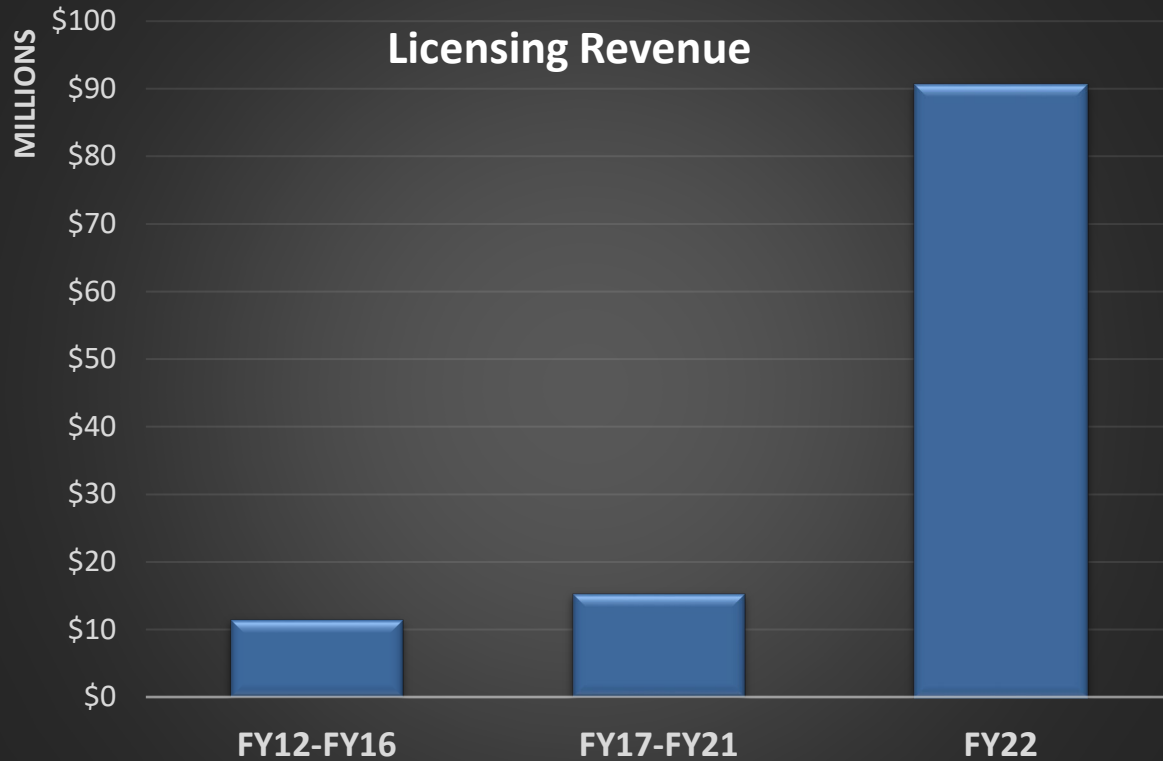
Summary of FY22 Performance



*Results based on cash received in the fiscal year

**Due principally to accrued patent expenses for Neumora and Chinook licenses, each of which was fully reimbursed.

Per Year Financial Metrics – Licensing Revenue, Sponsored Research, and Fixed Contract Value

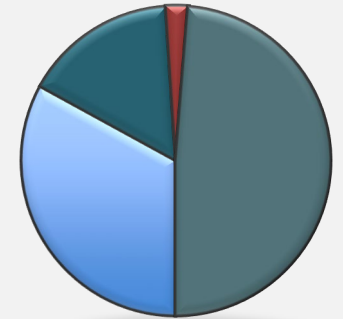


Metrics History - Revenue

Licensing Revenue



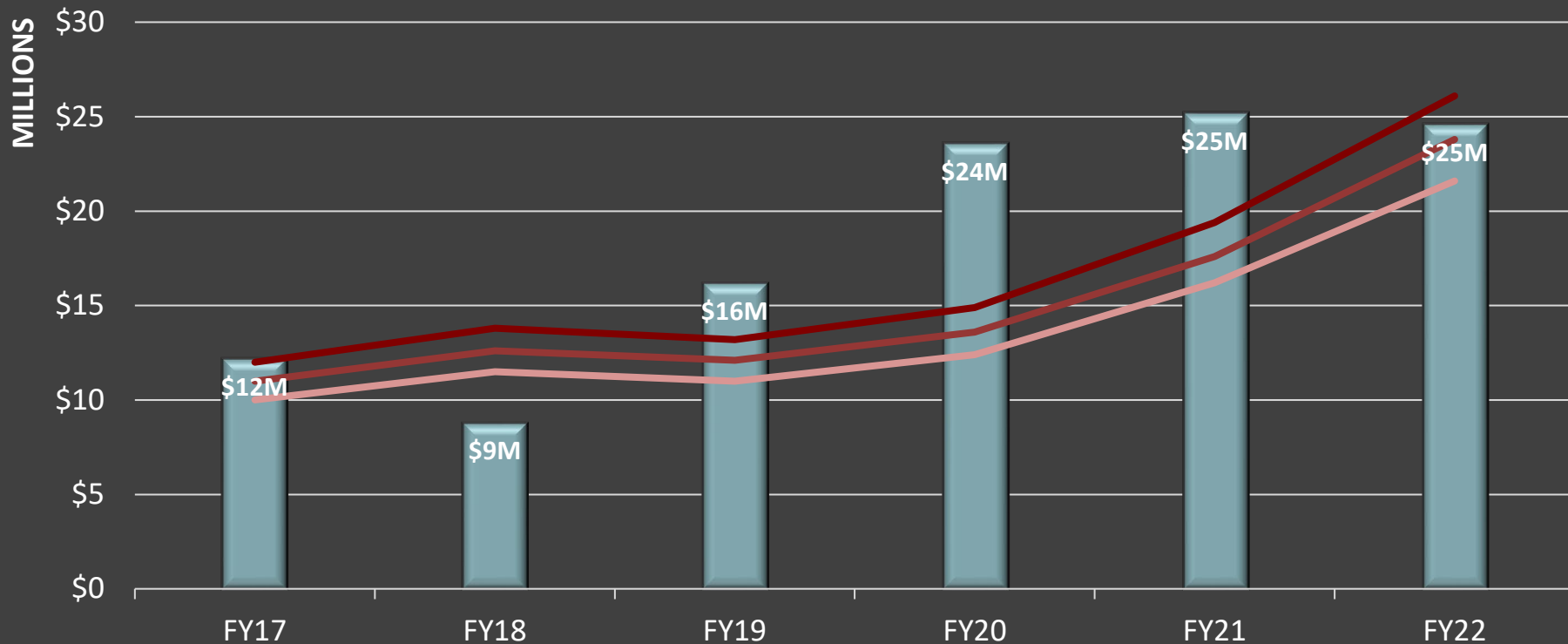
FY22 Revenue Mix



- Running Royalty
- Up-front Payments
- Patent Cost Reimbursements
- Other Payments

“Other Payments” include milestone payments, minimum annual royalties, equity liquidation, legal settlements, etc.

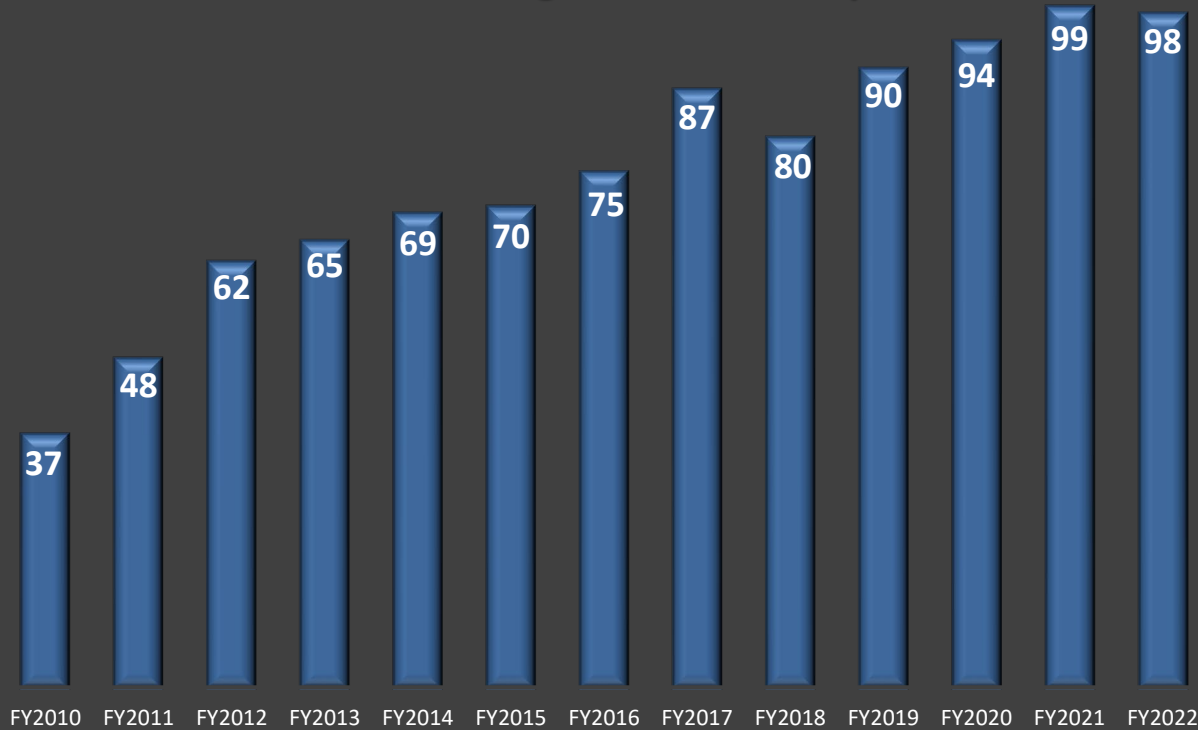
Industry Research Funding



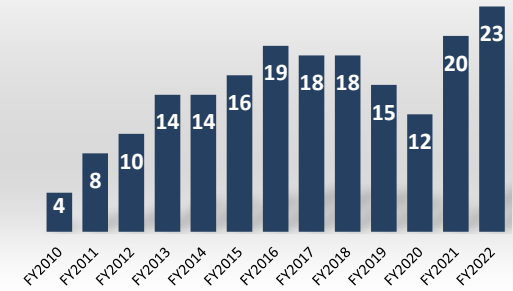
Metrics History - Transactions

Excluding end user Olinda software and materials reissue licenses 2015-17

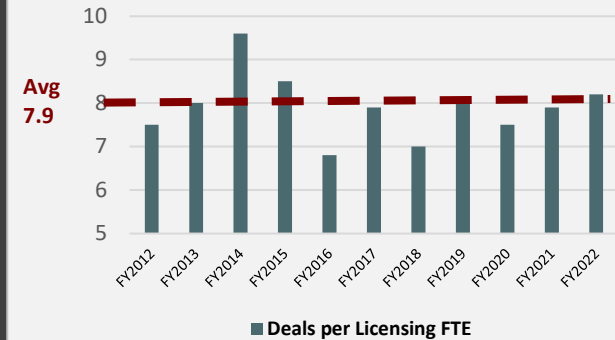
License Agreements Completed



Long term potential royalty-bearing exclusive licenses

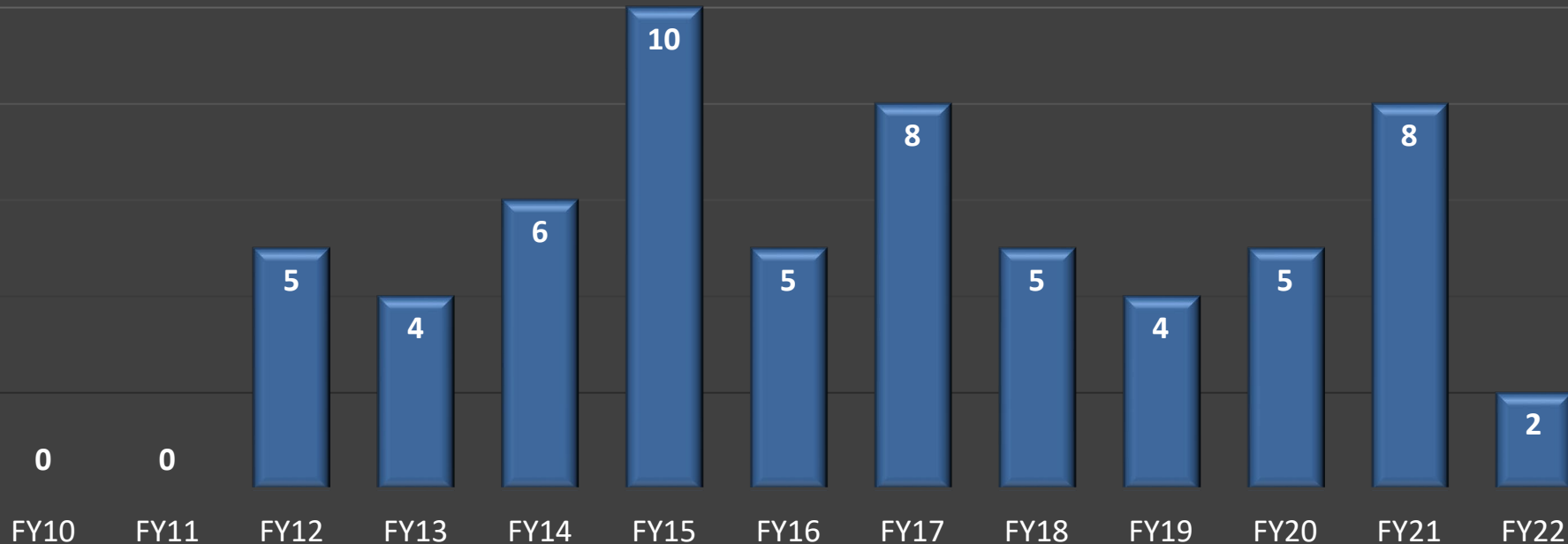


Deals per Licensing FTE



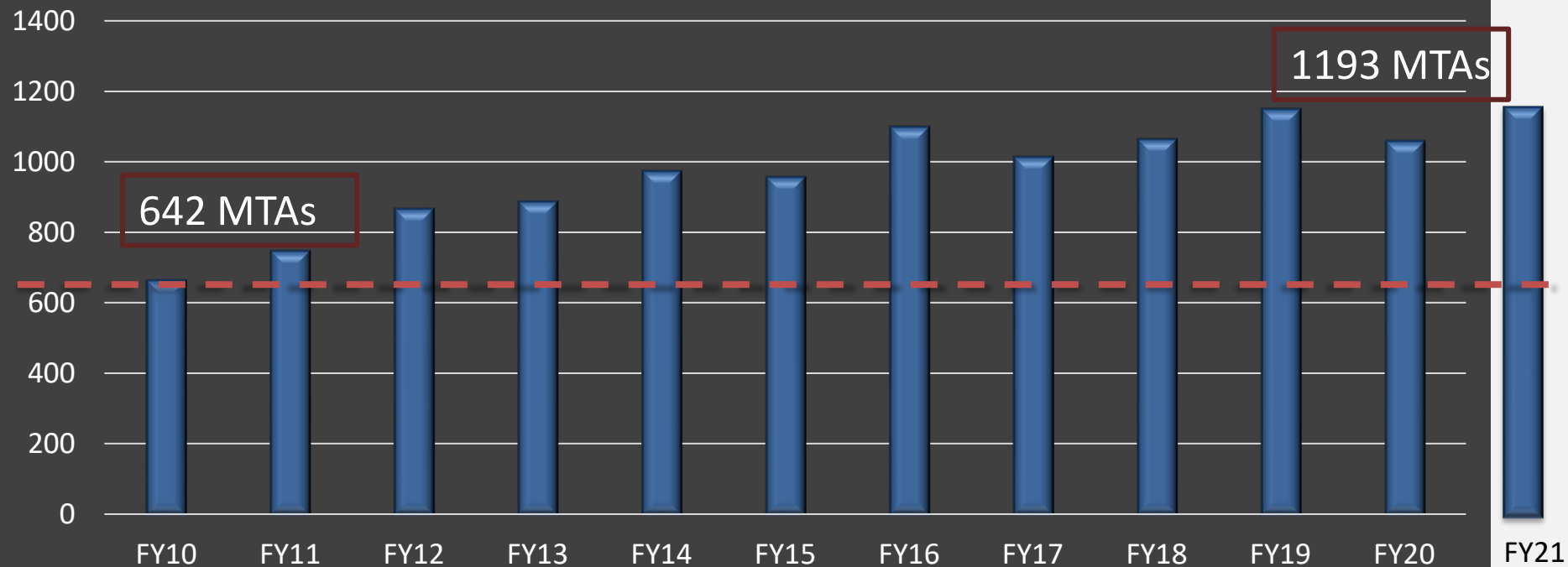
Metrics History - Startups

New Vanderbilt Start-ups



Support for Research: MTAs

95+% of MTAs processed are for SOM-related faculty



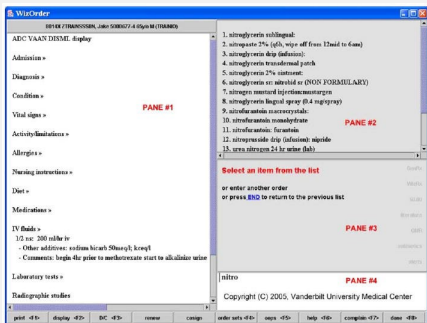


Automated Material Transfer Agreements

MTAShare is a comprehensive, automated system for rapidly creating, processing, executing, and managing MTAs through a browser-based web portal.

Exemplary commercialization successes

Notable Transactions & Products



McKesson
Horizon Expert Orders



Houghton Mifflin Harcourt
Read-180®



Potential Therapeutic
for Schizophrenia



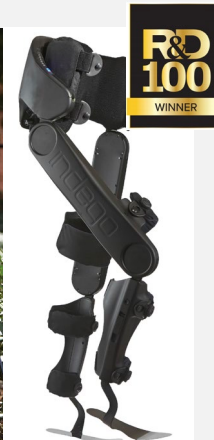
Energy Absorption
"Crash Cushions"



AstraZeneca
EVUSHELD™



Parker Hannifin
Indego®



A case for leveraging academic innovation

- Support the academic mission
- Generate positive societal impact
- Contribute to local economic development
- Generate revenue to support research
- Positively impact brand value
- Legally required by the Bayh-Dole Act

Innovation improves the quality of life for citizens and patients.

Since the public is paying for most of the research, it is important for them to see the benefits of innovations resulting from academic research in their lives.



Origins of
technology
transfer

- Prior to 1980, any invention made under a Government grant was owned by the US Government
- The Government generally did not take any action to protect and commercialize all of its thousands of inventions – no infrastructure
- **Under the Bayh-Dole Act**, universities, research institutions, and other not-for-profit organizations are allowed to own, protect, and commercialize their Federally-funded inventions

Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole act of 1980.

The Economist, Tech Quarterly
Q4, 2002

Why license technologies?

- **Improve quality of life for citizens and patients through new products and services**
- Increase research opportunities via collaborations and strategic partnerships
- Generate revenue for inventors and for Vanderbilt to support future research
- Create jobs and economic growth opportunities via start up companies
- Aid in with recruitment and retention of faculty
- Increase reputation/brand
- Invigorate the mind and spirit – for the experience
- **Achieve IMPACT**

Many Lifesaving or Life Improving Blockbuster Products or Companies Emerged from University Research



Why should researchers disclose?



VANDERBILT
UNIVERSITY
Technology Transfer

- Federal Government requires reporting of Federally funded inventions
- Vanderbilt requires disclosure as a condition of employment
- Discoveries that can help people and make a difference will rot on the vine without disclosure, protection and commercialization
- VU employees have a financial incentive – 40% of revenues from licensing inventions flow back to inventors

- Investigators and institutions have an obligation to report inventions to the federal government, and to grant the Government a free license to use for Government purposes
- OCM manages this in annual reports and grant close out reports
- CTTC reports inventions (*better match SPA's and OCM's reports!*), as well as election of title, patent filings, and utilization
- CTTC includes “reservation of rights clause for US Government” in license agreements, and reports government funding on face of patent applications

“Patenting has a positive effect on the rate of publications”

Azoulay, P., W. Ding and T. Stuart, 2009, “The Impact of Academic Patenting on the Rate, Quality, and Direction of (Public) Research”, *The Journal of Industrial Economics*, 57(4), 637-676.

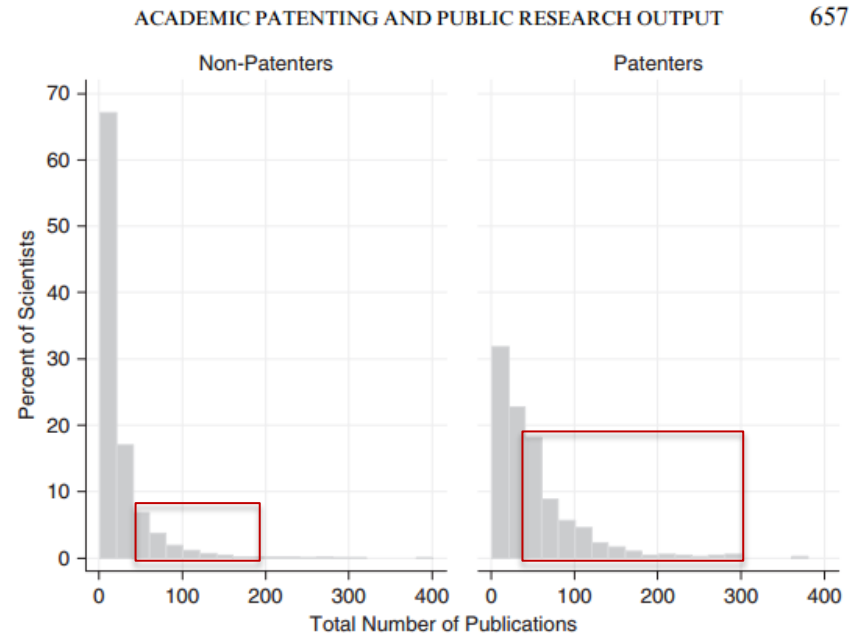


Figure 2
Distribution of Publication Count for Patenting and Non-Patenting Scientists

Academic inventors
“publish more and better
quality papers than their
non-patenting
colleagues”

Breschi, S., F. Lissoni and F. Montobbio, 2008,
“University patenting and scientific productivity.
A quantitative study of Italian academic
inventors”, *European Management Review* 5, 91-
110



University patenting and scientific productivity

96

Table 4 Scientific productivity of academic inventors and controls

	<i>N</i>	<i>Mean</i>	<i>Std. dev.</i>	<i>Median</i>
<i>Academic inventors</i>				
Chemical engineering**	63	2.0	1.75	1.5
Pharmacology *	83	2.2	1.21	2.0
Biology*	78	2.5	2.10	2.0
Electronic engineering	72	1.7	1.04	1.4
All fields	296	2.1	1.60	1.8
<i>Control professors</i>				
Chemical engineering	63	1.3	1.10	1.1
Pharmacology	83	1.7	1.11	1.6
Biology	78	1.8	1.27	1.5
Electronic engineering	72	1.3	1.18	1.0
All fields	296	1.6	1.28	1.3

“Inventors publish significantly more than their colleagues who work in similar fields and who have similar career characteristics.”

Van Looy B., K. Debackere and J. Callaert, 2006, “Publication and Patent Behaviour of Academic Researchers: Conflicting, Reinforcing or Merely Co-existing”, *Research Policy* 35, 596-608.

Vanderbilt IP Policy

- Policy on Technology and Literary and Artistic Works
- Governs ownership, protection and transfer of technology (including inventions, discoveries and other innovations) and literary and artistic works
- Discerns between scholarly and non-scholarly works
 - Scholarly work (publications) owned by author



VANDERBILT
Faculty Senate

Faculty Manual

**Snapshot as of
June 23, 2022**

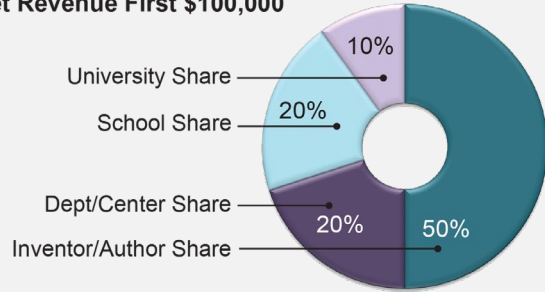
- Vanderbilt owns Technologies created:
 - Within scope of employment
 - With Significant Use of University Resources (facilities or funds administered by VU)
 - Works-for-hire
- Faculty and staff have obligation to disclose
- IP Policy applies to both VU and VUMC employees

- CTTC has responsibility for protection and licensing of Vanderbilt IP assets
 - Proceeds from licensing are distributed according to policy distribution schedule (next slide)
- If technology is not pursued by CTTC, inventors may request assignment back (a.k.a., “return of rights”)
 - Faculty advisory committee determined how rights would be returned, and conditions are on CTTC website

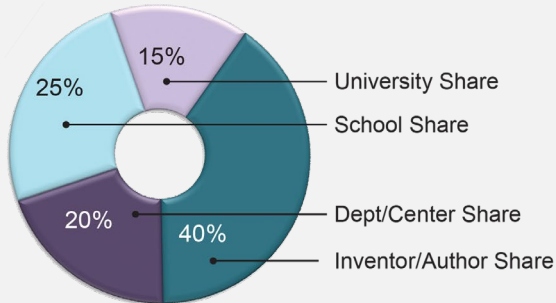
Revenue Distribution Policy

REVENUE DISTRIBUTION

Net Revenue First \$100,000






Net Revenue Above \$100,000




A portion of all technology licensing revenue is provided to the departments, centers and schools from where the technology originated, to support additional research


Vanderbilt Revenue Sharing Policy Among the Most Generous in the Country

		50% (first \$100k); 40% (>\$100k) Note: VU calculations based on <i>per-year</i> royalties. ⁽¹⁾
Dartmouth		50% [<i>after 15% admin fee plus direct expenses</i>]
Princeton		50% (first \$100k); 40% (\$100k-\$500k); 30% (>\$500k)
Yale		50% (first \$100k); 40% (\$100k-\$200k); 30% (>\$200k) [<i>after 10% admin fee plus direct expenses</i>]
UC Berkeley		50% (first \$100k); 35% (\$100k-\$500k); 20% (>\$500k) [<i>after 15% admin fee plus direct expenses</i>]
Duke		50% (first \$500k); 33% (\$500k-\$2mil); 25% (>\$2mil) [<i>after 10% admin fee plus direct expenses</i>]
Notre Dame		50% (first \$100k); 25% (>\$100k)
Columbia		50% (first \$100k); 25% (>\$100k) [<i>after 20% admin fee</i>]
Rice		37.5%
Wash U/ Hopkins	 	35% ⁽²⁾ [<i>Wash U - after 20% admin fee plus direct expenses</i>]
Harvard		35% [<i>after 15% admin fee</i>]
Cornell		33%
Emory		100% (first \$25k); 33% (\$25k-\$4mil); 25% (>\$4mil)
Stanford/Brown/MI	  	33% [<i>after 15% admin fee plus direct expenses</i>]
Northwestern		33% [<i>after 20% admin fee plus direct expenses</i>]
Penn		30% [<i>after pro rata share of tech transfer office costs plus direct expenses</i>]
Partners/Cornell/Cal Tech	  	25%


Dartmouth  50% (first \$100k); 40% (>\$100k) Note: VU calculations based on per-year royalties.
 50% [after 15% admin fee plus direct expenses]







50% (first \$100k); 40% (>\$100k) – no admin fees, restarts annually





50% (first \$500k); 33% (\$500k-\$2mil); 25% (>\$2mil) – after 10% admin fee



Emory  100% (first \$25k); 33% (\$25k-\$4mil); 25% (>\$4mil)


Stanford/Brown/MI    33% [after 15% admin fee plus direct expenses]

Northwestern  33% [after 20% admin fee plus direct expenses]


Penn  30% [after pro rata share of tech transfer office costs plus direct expenses]

Partners/Cornell/Cal Tech    25%









Dartmouth		50% (first \$100k); 40% (>\$100k) Note: VU calculations based on <u>per-year</u> royalties.
		50% [<u>after</u> 15% admin fee plus direct expenses]

















50% (first \$100k); 40% (>\$100k) – no admin fees, restarts annually



35% flat - after 20% admin fee

Cornell		33%
Emory		100% (first \$25k); 33% (\$25k-\$4mil); 25% (>\$4mil)
Stanford/Brown/MI	  	33% [<u>after</u> 15% admin fee plus direct expenses]
Northwestern		33% [<u>after</u> 20% admin fee plus direct expenses]
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Partners/Cornell/Cal Tech	  	25%

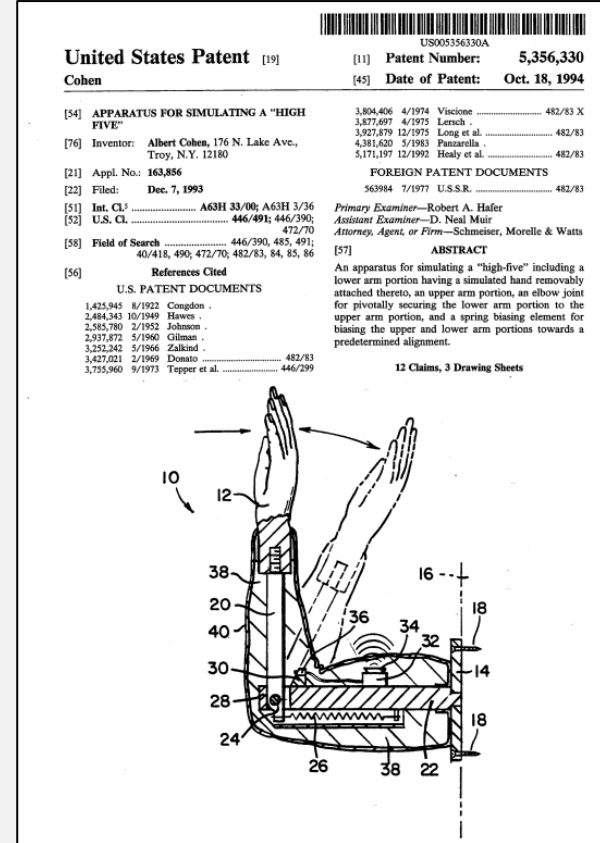
Vanderbilt v Emory

Dartmouth		50% (first \$100k); 40% (>\$100k) Note: VU calculations based on <u>per-year</u> royalties.
		50% [<u>after</u> 15% admin fee plus direct expenses]
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Types of Intellectual Property

What is intellectual property?

- Of the intellect; created in the mind
- Subject to protection under the law
- Ideas alone are not patentable, must be reduced to practice

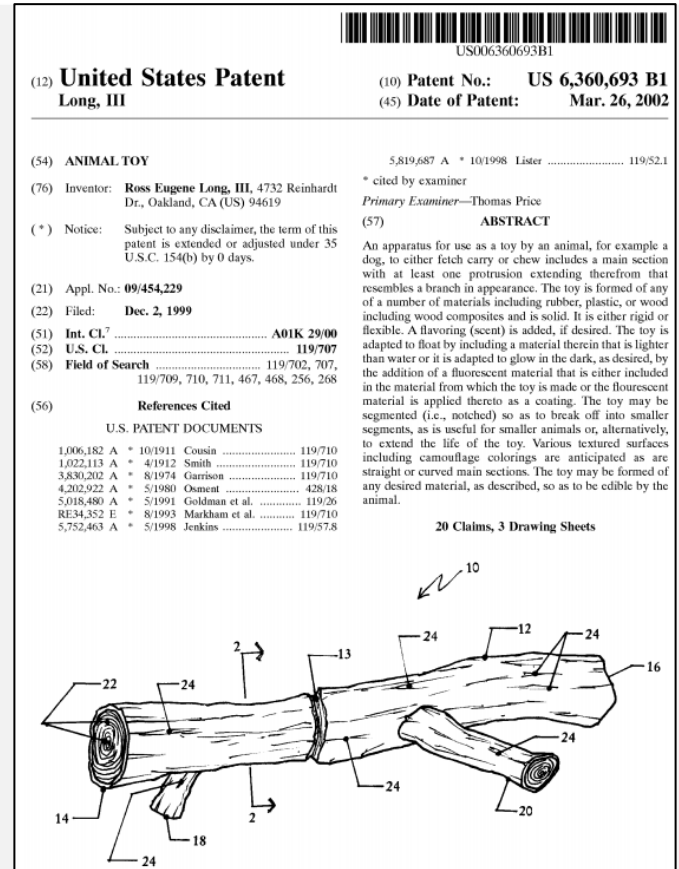


Article I, Section 8, Clause 8:

The 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**

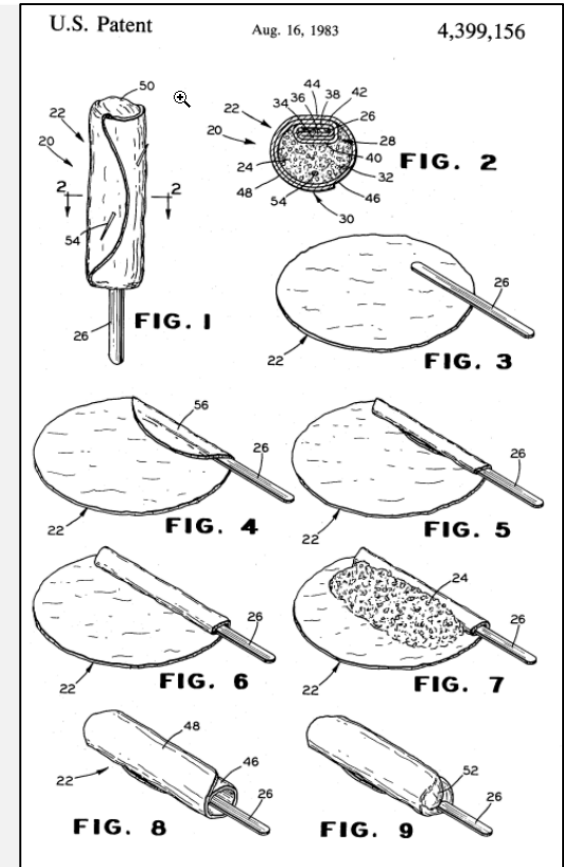
Key features of IP

- **Intangible** – “of the intellect”
- **Transferrable** – can be bought, sold, given
- **Limited monopoly** – can prevent others from using IP
- **Territorial** – IP typically protected jurisdiction by jurisdiction



Types of IP protection

- Patent
 - Invention & know-how
- Copyright
 - Original expression of an idea
- Trademark/Service Mark
 - Names & logos identifying source of goods/services
- Trade Secret
 - Information with economic value, secret



- A patent owner has the right to exclude all others from making, using, offering for sale or selling in, or importing the invention into, the United States
- If someone does any of these things without authority of the patent owner, they are infringing the patent

**A patent is a limited monopoly to commercially exploit an idea.
What ideas are patentable?**

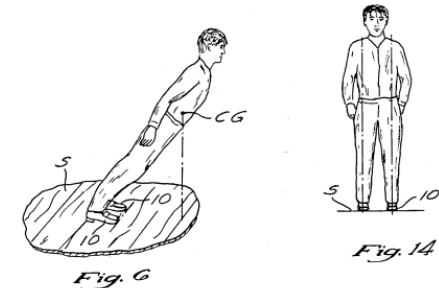
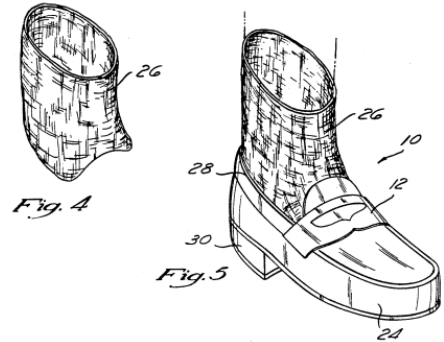
“Anything under the sun made by the hands of man”

- New chemical compounds, e.g., drugs, pesticides
- Methods of producing new compounds
- New uses for old compounds
- Purified natural materials, e.g., DNA, enzymes
- New formulations or mixtures, e.g., alloys, shampoo
- Transgenic animals or plants (excluding humans)
- Methods of performing a function by computer software
- Methods of doing business
- Methods of processing digital signals
- Tire tread pattern, clothing (design patents)

Patent Basics

- Utility patents
 - Can protect a process, machine, product, or composition of matter
 - Must be **useful, novel, and non-obvious**
 - Lasts for 20 years from the date of filing
 - Exclusive right - not an affirmative one!

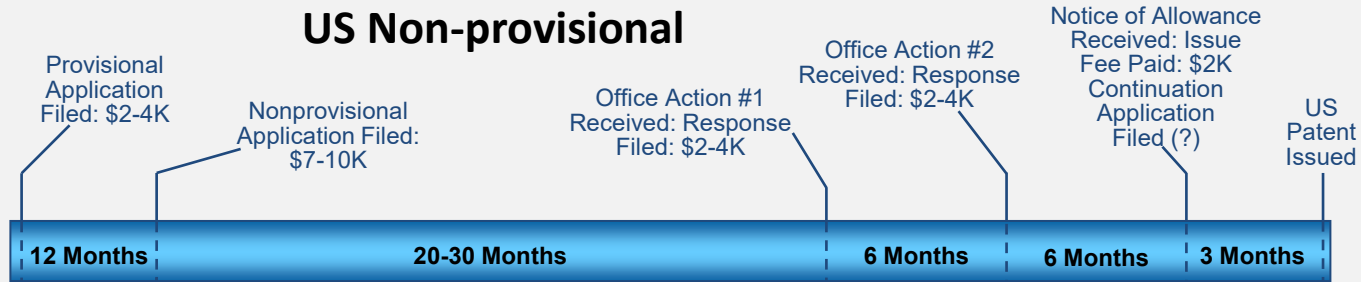
U.S. Patent Oct. 26, 1993 Sheet 2 of 4 5,255,452



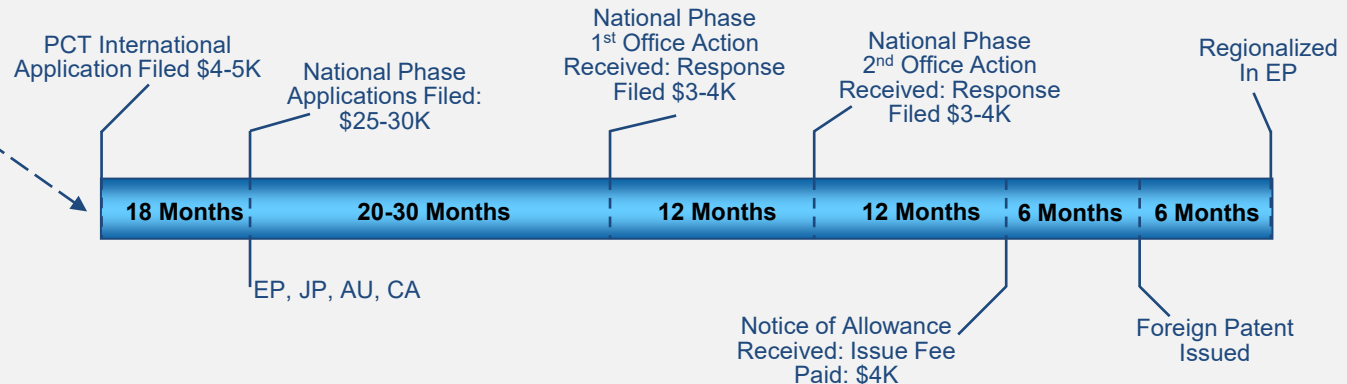
- **Useful** - demonstrated use or proposed use that one of “ordinary skill in the art” would believe
- **Novel** - Not fully described in one patent or publication (including your own) more than 1 year before you filed (the “prior art”)
- **Non-obviousness**: One of ordinary skill not motivated to combine prior art to reach the invention
- **Enablement**: One of ordinary skill can carry it out without “undue experimentation”
- **Best Mode**: Gives best known way of making and using it when application was filed

Patent prosecution timeline

US Non-provisional



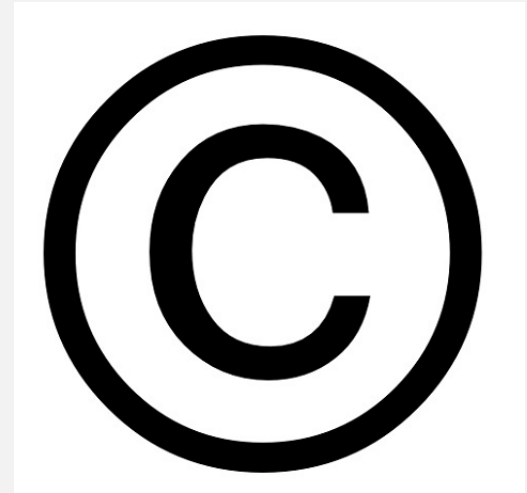
PCT



- As of March 16, 2013, the US became a first to file jurisdiction via the America Invents Act
- 12-month grace period in the US following public disclosure, no such protection for foreign rights
- Important to avoid any public disclosures prior to filing a patent application in order to preserve foreign rights
 - Sell or offer to sell
 - Use in public
 - Disclose to anyone outside your organization without NDA

- Patents are limited monopolies
- Patent applications typically take 1-2 months to draft and file
- Patents take **4-8 years** to secure
- Patents last for 20 years from first filing
- Patents are expensive:
 - **~\$25,000 in USA**
 - **~\$200,000 in EU, CA, AU, and JP**
- Disclosure of an idea before starting the patent process forfeits non-US rights and may jeopardize US rights as well !!!

- Exists from the time a work is created in fixed form
- Owner has exclusive right to control
 - Duplication or reproduction
 - Creation of derivative works
 - Distribution, public performance, or public display
- Duration of copyright protection (as of 1/1/1978)
 - Life of author plus 70 years
 - Corporate author - the shorter of 95 years from publication or 120 years from creation



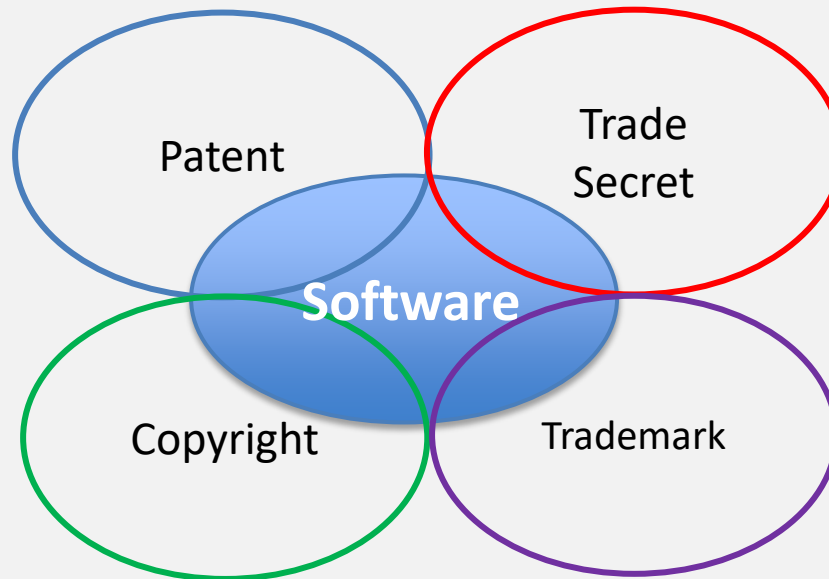
What is “copyrightable”?

- Work must be **original**
- Work must be created by an **author**
- Work must be **fixed** in a tangible medium of expression
- Examples: literary works, musical works, motion pictures, **software code**



What about software?

- Multiple forms of IP can be used to protect a single piece of software
- **What factors to consider when determining how to protect?**



Discussion